IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., et al.,	)	Volume V
Plaintiffs,	)	C.A. No. 21-1694-JLH
v.	)	
FINCH THERAPEUTICS GROUP, INC.,	)	
Defendant.	)	

Friday, August 9, 2024
8:47 a.m.

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE JENNIFER L. HALL
United States District Court Judge

APPEARANCES:

WOMBLE, BOND, DICKENSON, LLP
BY: MARY W. BOURKE, ESQ.

-and-

MORRISON & FOERSTER, LLP
BY: DARALYN DURIE, ESQ.
BY: MATTHEW A. CHIVVIS, ESQ.
BY: WHITNEY O'BYRNE, ESQ.
BY: RAMSEY FISHER, ESQ.

Counsel for the Plaintiff

APPEARANCES CONTINUED:

RICHARDS, LAYTON & FINGER, P.A.
BY: KELLY E. FARNAN, ESQ.
BY: SARA METZLER, ESQ.

-and-

KIRKLAND & ELLIS, LLP
BY: LESLIE M. SCHMIDT, ESQ.
BY: ADAM R. ALPER, ESQ.
BY: MICHAEL DeVRIES, ESQ.
BY: SHARRE LOTFOLLAHI, ESQ.
BY: PATRICIA CARSON, ESQ.
BY: ASHLEY ROSS, ESQ.
BY: ASHLEY CADE, ESQ.
BY: SAMUEL BLAKE, ESQ.

Counsel for the Defendant

08:47:05 COURT CLERK: All rise.

08:47:10 THE COURT: Hi. Good morning, everyone. Please
08:47:12 be seated.

08:47:13 So I understand there's a lingering issue about
08:47:17 whether or not the REBYOTA will go in. No?

08:47:25 MS. DURIE: We have resolved that, I believe.
08:47:25 By agreement, it did come in.

08:47:26 THE COURT: Okay. It's going to go back to the
08:47:28 jury room?

08:47:29 MS. DURIE: Yes.

08:47:30 THE COURT: Do we have any language that the

08:47:32 Court is supposed to read?

08:47:34 MS. DURIE: No, I'm happy -- I mean, I'm

08:47:35 happy -- I think we're happy to send it back.

08:47:37 THE COURT: Ok. I just wanted to put it on the

08:47:38 record that everybody is in agreement. Okay. Great.

08:47:40 MS. DURIE: There is one thing I wanted to do.

08:47:43 There is one exhibit, that by agreement, I wanted to move

08:47:44 into the record. It's PTX-938.

08:47:47 THE COURT: Okay.

08:47:48 MS. DURIE: And it is a duplicate of an exhibit

08:47:51 that's already in the record, but it got referred to by this

08:47:54 exhibit number. So we wanted to move it in by that exhibit

08:47:58 number as well.

08:48:00 THE COURT: Okay. Any objection?

08:48:00 MS. LOTFOLLAHI: No objection.

(PTX Exhibit No. 938 was admitted into

08:48:02 evidence.)

08:48:02 THE COURT: All right. We'll put it into

evidence.

08:48:02 We had some exhibits moved in yesterday, and

08:48:04 then this one today, outside the hearing of jury. Does

08:48:07 anyone have a concern with that? It's going to be in a

08:48:10 binder that goes back to the jury room.

08:48:12 MS. DURIE: I do not have a concern.

08:48:16 MR. DE VRIES: We do not, Your Honor.

08:48:17 THE COURT: All right. Very good.

08:48:17 I understand that the jurors are all here.

08:48:19 Are you all ready to get started?

08:48:26 MR. DE VRIES: We are, Your Honor.

08:48:48 THE COURT: Okay. Let's just get started then.

08:48:48 (Jury enters.)

08:49:49 THE COURT: All right. Please be seated.

08:49:53 I'm going to ask my courtroom deputy to please hand out copies of the final jury instructions.

08:50:16 All right. Ladies and gentlemen of the jury. I'm starting on page 1, which is after the table of contents.

08:50:25 1, General Instructions.

08:50:27 1.1, Introduction.

08:50:29 Members of the jury, now it is time for me to instruct you on the law that you must follow in deciding this case. I will start by explaining your duties and the general rules that apply in every civil case. Then, I will explain some rules that you must use in evaluating testimony and evidence. Then, I will explain the positions of the parties and the law you will apply in this case. Finally, I will explain the rules that you must follow during your deliberations in the jury room and the possible verdicts that you may return. Please listen carefully to everything I say. I will provide you with a copy of these

instructions.

You have two main duties as jurors. The first is to decide what the facts are from the evidence that you saw and heard in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way. Your second duty is to take the law that I give you, apply it to the facts, and decide which party should prevail on the issues presented.

I will instruct you about the burden of proof shortly. It is my job to instruct you on the law and you are bound by the oath you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that Judge Fallon gave you before the trial and the instructions that I've given during the trial, and these final instructions. All the instructions are important and you should consider them together as a whole.

Perform these duties fairly. Do not let any bias, sympathy or prejudice you may feel toward one side or the other influence your decision in any way.

Two, Evidence.

2.1, Evidence Defined.

You must make your decision based only on the evidence that you saw and heard here in the courtroom. Do

not let rumors, suspicion or anything else that you may have seen or heard outside of court influence your decision in any way. The evidence in this case includes only what the witnesses said while they were testifying under oath, including deposition testimony that has been played by video, the exhibits that I allowed into evidence, and any facts that the parties agreed to by stipulation. Nothing else is evidence.

The lawyers' statements, arguments, questions and objections are not evidence. None of my legal rulings, comments, or questions are evidence. Demonstrative exhibits are not evidence. Certain charts and graphics have been used to illustrate testimony from the witnesses. Unless I have specifically admitted them into evidence, these charts and graphics are not themselves evidence, even if they refer to, identify, or summarize evidence.

During the trial, I may not have let you hear the answers to some of the questions that the lawyers asked. I also may have ruled that you could not see some of the exhibits that the lawyers wanted you to see, and sometimes I may have ordered you to disregard things that you saw or heard. You must completely ignore all these things. Do not speculate about what a witness might have said or what an exhibit might have shown. These things are not evidence and you are bound by your oath not to let them influence your

decision in any way. Do not consider my rulings on whether you could hear certain testimony or see certain exhibits as any indication of my opinions of the case or what your verdict should be.

2.2, Direct and Circumstantial Evidence.

Some of you may have heard the terms "direct evidence" and "circumstantial evidence." Direct evidence is simply evidence like the testimony of an eyewitness, which, if you believe it, directly proves a fact. If the witness testified he saw it raining outside and you believed him, that would be direct evidence that it was raining.

Circumstantial evidence is simply a chain of circumstances that indirectly proves a fact. If someone walked into the courtroom wearing a raincoat, covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

It is your job to decide how much weight to give the direct and circumstantial evidence. The law makes no distinction as to the weight that you should give to either type of evidence, nor does it say that one is any better evidence than the other. You should consider all the evidence, both direct and circumstantial, and give it whatever weight you believe it deserves.

2.3, Consideration of Evidence.

You should use your common sense in weighing the evidence. Consider it in light of your every day experience with people and events, and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

3, Use of Notes.

You may use notes taken during the trial to assist your memory. Remember that your notes are for your personal use. They may not be given or read to anyone else. Do not use your notes or any other jurors' notes as authority to persuade fellow jurors. Your notes are not evidence and they are by no means a complete outline of the proceedings or a list of the highlights of the trial. Some testimony that is considered unimportant at the time presented and, thus, not written down may take on greater importance later in the trial considering all the evidence presented. Your notes are valuable only to refresh your memory. Your memory is what you should be relying on when it comes time to deliberate and render your verdict in this case.

4, Witnesses.

4.1. Credibility of Witnesses.

You, the jurors, are the sole judges of the credibility or the believability of the witnesses you have

seen during the trial and the weight their testimony deserves. You should carefully scrutinize all the testimony each witness has given and every matter of evidence that tends to show whether he or she is worthy of belief.

Consider each witness's intelligence, motive and state of mind, as well as his or her demeanor while on the stand. Consider the witness's ability to observe the matters as to which he or she has testified and whether he or she impresses you as having an accurate recollection of these matters.

Also, consider any relation each witness may bear to each side of the case, the manner in which each witness might be affected by the verdict, the witness -- excuse me -- the interest any witness may have in the verdict and the extent to which, if at all, each witness is either supported or contradicted by other evidence in the case.

Discrepancies in the testimony of different witnesses may or may not cause you to discredit such testimony. Two or more persons witnessing an incident or transaction may see or hear it differently. Likewise, in determining the weight to give to the testimony of a witness, you should ask yourself whether there was evidence tending to prove that the witness testified falsely about some important fact or whether there was evidence that at

some other time the witness said or did something or failed to say or do something that was different or inconsistent from the testimony that he or she gave during the trial.

It is the province of the jury to determine whether a false statement or a prior inconsistent statement discredits the witness's testimony. You should remember that a simple mistake by a witness does not mean that the witness was not telling the truth. People may tend to forget some things or remember other things inaccurately. If a witness has made a misstatement, you must consider whether it was simply an innocent lapse of memory or an intentional falsehood, and that may depend on whether it concerns an important fact or an unimportant detail.

4.2, Expert Witnesses. When knowledge of subject matter requiring special skill or knowledge in some science, profession or business that is not common to the average person might be helpful to the jury, a person who has special training or experience in that field, he or she is called an expert witness, is permitted to state his or her opinion on these matters.

However, you are not required to accept that opinion. As with any other witness, it is up to you to judge the credentials and credibility of the expert witness and decide whether to rely upon his or her testimony.

You should consider each expert opinion received

in evidence in this case and give it such weight as you think it deserves. If you decide that the opinion of an expert witness is not based upon sufficient education and experience or if you conclude that the reasons given in support of the opinion are not sound or if you feel that the opinion is outweighed by other evidence, you may disregard the opinion in whole or in part.

4.3, Deposition Testimony. During the trial, certain testimony was presented to you through depositions that were read into evidence or electronically played. This testimony must be given the same considerations you would give it had the witness personally appeared in court. Like the testimony of a live witness, the statements made in a deposition are made under oath and are considered evidence that may be used to prove particular facts.

5, The Parties and Their Contentions. I will now review for you the parties in this action and the positions of the parties that you will have to consider in reaching your verdict.

UMN and Finch allege that Ferring and Rebiotix, which I will refer collectively as "Ferring," infringes certain claims have three patents, specifically the '914 patent, which I may refer to as the "UMN patent," and the '309 and '080 patents. I will refer to all these patents collectively as the asserted patents. I may sometimes refer

09:00:44 to REBYOTA as the "accused product." UMN and Finch contend
09:00:51 that this infringement is willful. UMN and Finch seek
09:00:56 damages in the form of a reasonable royalty for this
09:00:59 infringement. In response to Finch and UMN's contentions,
09:01:05 Ferring contends it has not directly infringed or induced or
09:01:09 contributed to infringement. Ferring also argues that the
09:01:14 asserted claims are invalid. Because Ferring contends that
09:01:17 it has not infringed a valid claim, Ferring further contends
09:01:22 that Finch and UMN are not entitled to damages.

09:01:26 5.1, Burdens of Proof. In any legal action,
09:01:32 facts must be proven by a required standard of evidence
09:01:34 known as the burden of proof. In a patent case, such as
09:01:38 this, there are two different burdens of proof that are
09:01:42 used, the first is called preponderance of the evidence; the
09:01:46 second is called clear and convincing evidence.

09:01:48 UMN and Finch must prove their claims of patent
09:01:53 infringement by a preponderance of the evidence. That means
09:01:56 that UMN and Finch have to prove to you, in light of all the
09:02:01 evidence, that what they claim is more likely so than not.

09:02:04 To say it differently, if you were to put the
09:02:08 evidence favorable to UMN and Finch and the evidence
09:02:13 favorable to Ferring on opposite sides of the scale, UMN and
09:02:16 Finch would have to make the scale tip somewhat on its side.

09:02:19 If you find after considering all of the
09:02:22 evidence that a claim or a fact is more likely so than not

so, then the claim or fact has been proven by a preponderance of the evidence. UMN and Finch have alleged that Ferring infringes or has infringed the asserted patents that Ferring's infringement of any valid claim was willful and that it is entitled to damages to compensate it for any infringement.

UMN and Finch have the burden of proposing these allegations by a preponderance of the evidence. Ferring has alleged defenses and has also brought claims for relief against UMN and Finch called counterclaims. On these defenses and counterclaims, Ferring has a different burden of proof that is called clear and convincing evidence.

Clear and convincing evidence is evidence that produces in your mind a firm belief or conviction that the allegations sought to be proved by the evidence are true.

Clear and convincing evidence involves a higher degree of persuasion than is necessary to meet the preponderance of the evidence standard.

Ferring has alleged that the asserted claims are invalid. Ferring has the burden of proving these allegations by clear and convincing evidence. In determining whether any fact has been proven in the case, you may, unless otherwise instructed, consider the testimony of all witnesses, regardless of which party may have called them and all exhibits received in evidence, regardless of

which party may have produced them. You may have heard the phrase "proof beyond a reasonable doubt." That is a stricter standard of proof and it applies only in criminal cases. It does not apply to civil cases such as this one. You should, therefore, put it out of your mind.

6, The Claims of a Patent. Before you can decide the issues in the case, you need to understand the role of patent claims. The patent claims are numbered sentences at the end of the patent. The claims are important because the words of a claim define the scope of the patent right. The figures and text in the rest of the patent provide a description and/or examples of the invention and provide a context for the claims but the claims define the extent of the patent's coverage. Each claim may cover more or less than another claim, therefore, what a patent covers depends in turn on what each of its claims covers.

The patent claims involved here are Claim 7 of the '914 patent, Claims 16 and 21 of the '309 patent and Claims 2 and 9 of the '080 patent.

6.1, Independent and Dependent Claims. Claims can be stated in two different ways in a patent. The first way the patent claim can be stated is in the form of an independent claim.

An independent claim sets forth all the

09:05:20 requirements that must be met in order for an accused
09:05:22 product to be covered by that claim and thus, infringe that
09:05:26 claim. An independent claim is read alone to determine its
09:05:30 scope.

09:05:30 The second way a claim can be stated is in the
09:05:34 form of a dependent claim. A dependent claim does not
09:05:38 itself recite all the requirements of the claim but instead
09:05:42 incorporates the requirements of another claim or claims and
09:05:46 adds its own additional requirements. In this way, the
09:05:49 claim depends on another claim or claims.

09:05:53 To determine what a dependent claim covers, it
09:05:57 is necessary to look at both the dependent claim and any
09:06:00 other claims from which it depends.

09:06:03 In this case, Claim 7 of the '914 patent, Claims
09:06:08 16 and 21 of the '309 patent and Claims 2 and 9 of the '080
09:06:13 patent are dependent claims.

09:06:17 6.2, Construction of Claims. The law says that
09:06:21 it is the Court's duty to define the terms of patent claims.
09:06:26 I have already defined the meaning of some of the words of
09:06:29 the patent claims that you are considering in this case.
09:06:32 You must accept my definition of these words in the patent
09:06:36 claims as correct. You must use the definitions I give you
09:06:40 for each claim to make your decisions as to whether the
09:06:44 claim is infringed or invalid.

09:06:46 You must ignore any different definitions used

09:06:49 by the witnesses or the attorneys. You should not take my
09:06:53 definition of the language of the patent claims as an
09:06:56 indication that I have a view regarding how you should
09:07:00 decide the infringement or invalidity issues that you are
09:07:03 being asked to decide. These issues are yours to decide.
09:07:09 The terms with specific definitions are listed
09:07:12 below. The definitions for these terms were also provided
09:07:16 separately in your juror notebooks. When I have not defined
09:07:19 a term, you should give it its ordinary meaning as the term
09:07:23 would have been understood by a person of ordinary skill in
09:07:26 the art.
09:07:28 Rough particulate matter, '309 patent. Rough
09:07:34 macroscopic nonliving matter, separated from rough
09:07:40 particulate matter, '309 patent. Separated from rough
09:07:44 macroscopic nonliving matter. Effective amount, '914
09:07:50 patent, a sufficient amount to provide the desired effect.
09:07:56 Amount effective, '309 patent. A sufficient amount to
09:08:01 provide the desired effect. At least six different classes
09:08:08 of bacteria selected from the group consisting of
09:08:13 Actinobacteria, Bacteroidia, Bacilli, Clostridia,
09:08:27 Erysipelotrichia, Alphaproteobacteria, Betaproteobacteria,
09:08:35 Gammaproteobacteria, Mollicutes and Verrucomicrobia. '914
09:08:43 patent a Markush group for which no construction is
09:08:47 necessary.
09:08:48 Extract, '914 patent, a substance obtained from

a material mixture, organisms or part of an organisms by some chemical and/or physical process. Fecal preparation, '914 patent, plain and ordinary meaning.

7, Infringement.

7.1, Generally. A person, any person or business entity that makes, uses, sells, offers for sale or imports the patented invention in the United States during the term of the patent without the patent owner's permission, infringes the patent. I will now instruct you how to decide whether or not UMN and Finch have proven that Ferring had infringed the asserted patent through its REBYOTA product.

Infringement is assessed on a claim-by-claim basis, therefore, there may be infringement as to one claim, but no infringement as to another. In this case, there are three possible ways that a claim may be infringed. The three types of infringement are called, one, direct infringement; two, active inducement; and three, contributory infringement.

Active inducement and contributory infringement are referred to as indirect infringement. There cannot be indirect infringement without someone else engaging in direct infringement. In this case, UMN and Finch have alleged that Ferring directly infringes Claims 16 and 21 of the '309 patent and Claims 2 and 9 of the '080 patent. In

addition, UMN and Finch have alleged that healthcare providers directly infringe Claim 7 of the '914 patent and Ferring is liable for actively inducing or contributing to that direct infringement by healthcare providers.

In order to prove infringement, UMN and Finch must prove that the requirements for one or more types of these infringements are met by a preponderance of the evidence. That is, that it is more likely than not that all of the requirements for one or more of each of these types of infringement have been proved.

Having one's own patent or patent application is not a defense to infringing another's patent. Accordingly, whether Ferring has patents or patent applications and whether any of these patents or patent applications cover REBYOTA, should not be considered in your determination of whether Ferring infringes the asserted patents.

I will now explain each of the types of infringement in more detail.

7.2, Direct Infringement by Literal Infringement. There are two types of direct infringement. One, literal infringement; and two, infringement under the doctrine of equivalents. In order to prove direct infringement by literal infringement, UMN and Finch must prove by a preponderance of the evidence, i.e., that it is more likely than not that Ferring made, used, sold, offered

09:12:10 for sale within or imported into the United States, a
09:12:12 product or method that meets all of the requirements of a
09:12:16 claim and did so without the permission of Finch during the
09:12:20 time the patent was enforced. You must compare the product
09:12:24 or method with each and every one of the requirements of a
09:12:27 claim to determine whether all of the requirements of that
09:12:30 claim are met. You must determine separately for each
09:12:33 asserted claim whether or not there is infringement.
09:12:37 For dependent claims, if you find that a claim
09:12:39 to which a dependent claim refers is not infringed, there
09:12:44 cannot be infringement of that dependent claim. On the
09:12:48 other hand, if you find that an independent claim has been
09:12:50 infringed, you must still decide separately whether the
09:12:55 product or method meets the additional requirements of any
09:12:58 claims that depend from the independent claim to determine
09:13:01 whether those dependent claims have also been infringed.
09:13:05 A dependent claim includes all the requirements
09:13:09 of any of the claims to which it refers, plus additional
09:13:12 requirements of its own. The relevant comparison for
09:13:15 infringement is between Ferring's product and UMN and
09:13:19 Finch's patent claims, not with any product of UMN or Finch.
09:13:25 A party can directly infringe a patent without knowing of
09:13:28 the patent or without knowing that what the party is doing
09:13:31 is patent infringement.
09:13:33 7.3, Direct Infringement by Doctrine of

Equivalents. If a person makes, uses, sells, offers to sell within or imports into the United States, a method that does not literally meet all of the elements of a claim and thus does not literally infringe that claim, there can still be direct infringement if that method satisfies the claim elements under the doctrine of equivalents.

Under the doctrine of equivalents, a method infringes a claim if the accused method has steps that literally meet or are equivalent to each and every element of the claim. You may find that an element or step is equivalent to an element of a claim that is not met literally if a person having ordinary skill in the field of technology of the patent would have considered the differences between them to be insubstantial or would have found that the element used in the accused method, one performs substantially the same function; and two, works in substantially the same way; three, to achieve substantially the same result as the element of the claim.

In order to prove infringement by equivalents, UMN and Finch must prove the equivalency of the element used in the accused method to the claim elements by a preponderance of the evidence. Thus, each element of a claim must be met by the method either literally or under the doctrine of equivalents for you to find infringement.

7.4, Infringement of Comprising Claims.

09:15:23 The preamble to the asserted claims used the
09:15:26 phrase "comprising." The word "comprising" means including
09:15:30 the following, but not excluding others. If you find that
09:15:35 the accused product or method includes all the elements or
09:15:38 method steps in an asserted claim, even if the accused
09:15:42 product or method includes additional components or method
09:15:46 steps, then the accused product or method literally
09:15:49 infringes that claim.
09:15:51 7.5, Actively Inducing Patent Infringement.
09:16:00 UMN and Finch allege that Ferring is liable for
09:16:02 infringement by actively inducing healthcare providers to
09:16:06 directly infringe Claim 7 of the '914 patent, either
09:16:10 literally or under the doctrine of equivalents.
09:16:14 To establish that Ferring actively induced
09:16:17 infringement, UMN and Finch must prove by a preponderance of
09:16:21 the evidence that, A, a single actor, here, a healthcare
09:16:26 provider is responsible for direct infringement, namely, all
09:16:29 of the method steps of Claim 7 of the '914 patent and, B,
09:16:34 Ferring actively induced these acts of infringement by
09:16:38 healthcare providers.
09:16:41 To prove active inducement, UMN and Finch must
09:16:44 establish that it is more likely than not that:
09:16:47 1, Ferring aided instructed or otherwise acted
09:16:54 with the intent to cause acts by healthcare providers that
09:16:56 would constitute direct infringement of the patent.

09:16:59 2, Ferring knew of the patent or showed willful
09:17:03 blindness to the existence of the patent at that time.
09:17:06 3, Ferring knew or showed willful blindness that
09:17:10 the actions of the healthcare providers would infringe Claim
09:17:14 7 of the '914 patent.
09:17:15 4, Healthcare providers infringe Claim 7 of the
09:17:21 '914 patent.
09:17:22 UMN and Finch must prove all four elements to
09:17:25 establish infringement. To find willful blindness, 1,
09:17:31 Ferring must have subjectively believed that there was a
09:17:36 high probability that a fact existed and, 2, Ferring must
09:17:40 have taken deliberate actions to avoid learning of that
09:17:44 fact.
09:17:44 In order to find Ferring liable for induced
09:17:47 infringement of an asserted claim, you must find direct
09:17:50 infringement of that claim by another. If there is no
09:17:53 direct infringement by anyone, there can be no induced
09:17:57 infringement. However, in order to establish active
09:18:00 inducement of infringement, it is not sufficient that
09:18:03 another directly infringes the claim, nor is it sufficient
09:18:07 that Ferring was aware of the acts by others that allegedly
09:18:12 constitute the direct infringement.
09:18:14 If you find that Ferring was aware of the patent
09:18:17 but believe that the acts it encouraged did not infringe
09:18:20 that patent, Ferring cannot be liable for inducement. The

mere fact, if true, that Ferring knew or should have known that there was a substantial risk that the healthcare providers' acts would infringe the '914 patent would not be sufficient to support a finding of active inducement of infringement.

7.6, Contributory Infringement.

UMN and Finch also assert that Ferring has contributed to infringement of Claim 7 of the '914, by another person by selling, offering for sale or importing into the United States, a component for use in an infringing method. To establish contributory infringement, UMN and Finch must prove that it is more likely than not that Ferring had knowledge of both the patent and direct infringement of that patent.

UMN and Finch must also prove that each of the following is more likely than not:

1. Others infringed the asserted claims, namely, others performed in the United States all of the steps of the asserted claims.

2. Ferring sold, offered for sale or imported within the United States, a component for use in the infringing method.

3. The component is not a staple article or commodity of commerce capable of substantial non-infringing use.

4. The component constitutes a material part of the claimed invention.

And, 5. Ferring knew or was willfully blind to the fact that the component was especially made or adapted for use in an infringing method.

A staple article or commodity of commerce capable of substantial non-infringing use is something that has uses other than as part or component of the patented product or in the patented method and those other uses are not occasional, far-fetched, impractical, experimental or hypothetical.

Ferring's knowledge that the component was especially made or adapted for use in an infringing product or method may be shown with evidence of willful blindness. As with inducement, to find willful blindness, you must find that Ferring subjectively believed there was a high probability that a fact existed and Ferring took deliberate actions to avoid learning of that fact.

8, Willful Infringement.

To prove willful infringement, UMN and Finch must first persuade you by a preponderance of the evidence that Ferring infringed a valid claim of the asserted patents. The requirements for proving such infringement were discussed earlier in my instructions.

In addition, to prove willful infringement of a

claim, UMN and Finch must persuade you that it is more likely true than not true that Ferring knew of the asserted patents and intentionally infringed at least one asserted claim of the patent.

For example, you may consider whether Ferring's behavior was deliberate or intentional. However, you may not find that Ferring's infringement was willful, merely because Ferring knew about the patents without more. Rather, to show willfulness, you must find that Ferring engaged in additional conduct evidencing deliberate or reckless disregard of UMN and Finch's patent rights.

In determining whether UMN and Finch have proven that Ferring's infringement was willful, you must consider all of the circumstances and assess Ferring's knowledge at the time the challenged conduct occurred. Willfulness can be established by circumstantial evidence. If you determine that any infringement was willful, you may not allow that decision to affect the amount of any damages award you give for infringement.

9, Invalidity.

Ferring contends that all of the asserted claims of the asserted patents are invalid. Ferring must prove by clear and convincing evidence that each asserted claim is invalid. Ferring contends that the asserted claims are invalid for the following reasons.

09:22:21 Ferring contends that Claim 16 and 21 of the '309 patent and Claims 2 and 9 of the '080 patent are invalid as obvious in view of the prior art. Ferring contends that Claim 7 of the '914 patent and Claims 2 and 9 of the '080 patent are invalid because the specification of the patent does not contain an adequate written description of the claimed invention.

I will explain the legal concepts of invalidity in a moment. In making your determination, you must consider each of the patent claims separately and individually. Even if you find one patent claim invalid, other claims of the same patent may still be valid.

9.1, Prior Art.

Under the patent laws, a person is granted a patent only if the invention claimed in the patent is new and not obvious in light of what came before. Prior art is a legal term used to describe what others had done in the field before the invention was made. It is not necessary that the prior art has been available to every member of the public, but it must have been available without restriction to that segment of the public most likely to avail itself of the prior art contents.

Prior art includes any of the following items received into evidence during trial:

1. Any product that was in public use or on

sale in the United States before the invention was made.

2. Any patents that issued more than one year before the filing date of the patent or before the invention was made.

3. Any publications having a date more than one year before the filing date of the patent or publicly accessible in the United States before the invention was made.

4. Any product that was in public use or on sale in the United States more than one year before the patent was filed.

Or, 5. Any product described in an issued United States patent filed by another person before the invention of the patents.

If the patent office considered a reference, it may be more difficult for Ferring to meet its burden to prove invalidity based on that reference. If the patent office did not have all material facts before it, Ferring's burden to prove invalidity by clear and convincing evidence may be easier to sustain.

9.2, Validity of the Independent and Dependent Claims.

You must evaluate the invalidity of each asserted claim separately. Even if an independent claim is invalid, this does not mean that the dependent claims that

depend from it are automatically invalid. However, if you find that a dependent claim is invalid, then you must find that the independent claim from which it depends is also invalid.

9.3, Person of Ordinary Skill.

The question of invalidity of a patent claim is determined from the perspective of a person of ordinary skill in the art, also referred to as a POSA in the field of the claimed invention as of the effective filing date. When determining the level of ordinary skill in the art, you should consider all the evidence submitted by the parties including evidence of:

1. The level of education and experience of persons actively working in the field as of the time of the invention.

2. The types of problems encountered in the field.

3. Prior art solutions to those problems.

4. Rapidity with which innovations were made in the art at the time.

And, 5. The sophistication of the technology.

9.4, Obviousness.

As I explained previously, under the patent laws a person is granted a patent only if the invention claimed in the patent is both new and not obvious in light of what

09:26:23 came before. Even though an invention may not have been
09:26:26 identically disclosed or described before it was made by an
09:26:30 inventor, in order to be patentable, an invention must not
09:26:35 have been obvious to a person of ordinary skill in the art
09:26:37 at the time the invention was made. Obviousness may be
09:26:40 shown by considering one or more than one item of prior art.
09:26:46 In this case, Ferring contends that Claims 16
09:26:52 and 21 of the '309 patent and Claims 2 and 9 of the '080
09:26:56 patent are invalid as obvious over the prior art and the
09:27:01 knowledge of a person of skill in the art. Ferring must
09:27:05 prove by clear and convincing evidence that the asserted
09:27:08 claims of the patents would have been obvious to a person of
09:27:13 ordinary skill in the art at the time the invention was
09:27:15 made. The issue is not whether the asserted claims would
09:27:19 have been obvious to you as a layperson, to me as the judge
09:27:21 or to a genius in the field of microbiology, but whether it
09:27:26 would have been obvious to one of ordinary skill in the art
09:27:29 at the time the invention was made.
09:27:31 In determining whether an asserted claim would
09:27:34 have been obvious, you must avoid using hindsight. That is,
09:27:38 you should not consider what is known today or what was
09:27:40 learned from the teachings of the asserted patents. You
09:27:45 should not use the patent as a road map for selecting and
09:27:48 combining items of prior art. You must put yourself in the
09:27:53 place of a person of ordinary skill in the art at the time

the invention was made.

In determining whether an asserted claim would have been obvious, you must consider:

1. The scope and content of the prior art.

2. The differences, if any, between the claimed invention and the prior art.

3. The level of ordinary skill in the art at the time of the invention.

And, 4. Additional considerations, if any, that indicated that the invention was obvious or not obvious.

To determine the scope and content of the prior art, you must determine what prior art is reasonably pertinent to the particular problems the inventors faced. The person of ordinary skill in the art is presumed to be aware of all the pertinent prior art.

I have already instructed you how you are to determine the level of ordinary skill in the art. Once you have made that determination, you are to apply it in your determination of whether the asserted claims would have been obvious.

The next factor that you must consider is the differences between the prior art and the asserted claims. Importantly, a claim is not proved obvious merely by demonstrating that each of the claim requirements was independently known in the prior art. Most, if not all,

09:29:16 inventions rely on building blocks of prior art and claims
09:29:21 discovery almost of necessity will likely be combinations of
09:29:22 what is already known.
09:29:24 Therefore, you should consider whether a reason
09:29:27 existed at the time of the invention that would have
09:29:30 prompted a person of ordinary skill in the art to combine
09:29:33 the known elements in the way the asserted claims do. The
09:29:38 reason could come from the prior art, the background
09:29:41 knowledge of one of ordinary skill in the art, the nature of
09:29:45 any problem or need to be addressed, market demand or common
09:29:50 sense.
09:29:50 If you find that a reason existed at the time of
09:29:53 the invention to combine the elements of the prior art to
09:29:56 arrive at the claimed invention and there would have been a
09:29:59 reasonable expectation of success for doing so, this
09:30:03 evidence would make it more likely that the claimed
09:30:06 invention was obvious.
09:30:08 9.5, Objective Evidence of Non-Obviousness.
09:30:15 Before deciding the issue of obviousness or
09:30:18 non-obviousness for Claims 16 and 21 of the '309 patent, in
09:30:23 Claims 2 and 9 of the '080 patent, you must also consider
09:30:29 certain real world factors which if established, may
09:30:32 indicate that the invention would not have been obvious. No
09:30:36 factor alone is dispositive and you must consider the
09:30:40 obviousness or non-obviousness of the invention as a whole.

09:30:46 Certain of these factors include:

09:30:48 1. Were products covered by the claim commercially successful due to the merits of the claimed invention rather than due to advertising, promotion, salesmanship or features of the product, other than those found in the claim?

09:31:03 2. Was there a long-felt need for a solution to the problem facing the inventors, which was satisfied by the claimed invention?

09:31:12 3. Did others try but fail to solve the problem solved by the claimed invention?

09:31:19 4. Did others copy the claimed invention of the asserted claims of the '309 and '080 patents?

09:31:28 5. Did the claimed invention achieve unexpectedly superior results over the closest prior art?

09:31:34 6. Did others in the field or Ferring praise the claimed invention or express surprise at the making of the claimed invention?

09:31:44 7. Did others accept licenses under the asserted patents because of the merits of the claimed invention?

09:31:50 Answering all or some of these questions "yes" may suggest that the claim was not obvious. These factors are relevant only if there is a connection or nexus between the factor and the invention covered by the claim. Even if

you conclude that some of the above factors have been established, those factors should be considered along with all the other evidence in the case in determining whether Ferring has proven that the claimed invention would have been obvious.

9.6, Written Description.

The patent law contains certain requirements for the part of the patent called the specification. Ferring contends that Claims 2 and 9 of the '080 patent and Claim 7 of the '914 patent are invalid because the specification of the patent does not contain an adequate written description of the claimed invention. Ferring must prove by clear and convincing evidence that the claim did not satisfy the written description requirement. A patent must contain a written description of the claimed invention. The written description requirement helps to ensure that the patent applicant actually invented the full scope of the claimed subject matter. To satisfy the written description requirement, the patent specification must describe every limitation of a patent claim in sufficient detail, although the exact words found in the claim need not be used.

When determining whether the specification discloses the invention, the claim must be viewed as a whole from the viewpoint of a person having ordinary skill in the field of technology of the patent. The written description

requirement is satisfied if a person having ordinary skill in the art, reading the original patent application, would have recognized that the specification describes the full scope of the claimed invention as it is finally claimed in the issued patent and that the inventor possessed the subject matter finally claimed in the patent on or before the effective filing date. The specification must describe the full scope of the claimed invention, including each element thereof, either expressly or inherently.

A claimed element is disclosed inherently if a person having ordinary skill in the field, as of the effective filing date, would have understood that the element is necessarily present in what the specification discloses. That a person having ordinary skill in the art could have envisioned the claim invention does not satisfy the written description requirement.

It is unnecessary to spell out every detail of the invention in the specification and specific examples are not required, only enough must be included in the specification to convince persons of ordinary skill in the art that the inventor possessed the full scope of the invention.

In evaluating whether the specification has provided an adequate written description, you may consider factors such as: The nature and scope of the patent claims;

the complexity, predictability and maturity of the technology at issue; the existing knowledge in the relevant field; and the scope and content of the prior art.

The issue of written description is decided on a claim-by-claim basis, not as to the entire patent or groups of claims. If you find that Ferring has proven by clear and convincing evidence that the '914 patent does not contain adequate written description for Claim 7 or that the '080 patent does not contain adequate written description for Claims 2 or 9, then you must find that those claims are invalid.

10, Damages.

10.1, Damages Generally, Introduction.

If you find that Ferring infringed any of the asserted claims and that Ferring has failed to show that those asserted claims are invalid, you must then consider what amount of damages to award to UMN and Finch.

I will now instruct you about the measure of damages. If you find that Ferring has not infringed any valid claim of the asserted patents, then UMN and Finch are not entitled to any damages. By instructing you on damages, I am not suggesting which party should win this case on any issue. The damages you award must be adequate to compensate UMN and Finch for any infringement you determine to have occurred. They are not meant to punish an infringer.

09:36:20 Your damages award, if you reach this issue, should put UMN and Finch in approximately the same financial position that they would have been in if the parties had reached agreement for Ferring to license the asserted patents before the infringement began.

09:36:36 Specifically, the patent laws provide that damages for infringement may not be less than a reasonable royalty. You may not add anything to the amount of damages to punish an accused infringer or to set an example. You also may not add anything to the amount of damages for interest.

09:36:54 UMN and Finch have the burden to prove the amount of their damages by a preponderance of the evidence. While UMN and Finch are not required to prove the amount of their damages with mathematical precision, they must prove them with reasonable certainty. You may not award damages that are speculative, damages that are only possible, or damages that are based on guesswork.

09:37:19 10.2, Notice Date For Damages.

09:37:23 If infringement is found, the date of the hypothetical negotiation would be November 30th, 2022, the date that REBYOTA was approved by the FDA. If infringement is found, damages would begin on the date that Ferring first infringed.

09:37:41 10.3, Reasonable Royalty as a Measure of

09:37:47 Damages.

09:37:47 If you find that a patent claim is both
09:37:50 infringed and not invalid, then you must consider the issue
09:37:53 of a reasonable royalty for sales that infringed a claim of
09:37:57 a valid patent.

09:37:58 A royalty is a payment made to a patent holder
09:38:01 in exchange for the right to make, use, or sell the claimed
09:38:06 invention. A reasonable royalty is the amount of royalty
09:38:09 payment that a patent holder and the alleged infringer would
09:38:13 have agreed to in the hypothetical negotiation, taking place
09:38:17 at a time prior to when the allegedly infringing conduct
09:38:21 first began.

09:38:22 In considering this hypothetical negotiation,
09:38:24 you should focus on what the expectations of the patent
09:38:27 holder and the alleged infringer would have been had they
09:38:30 entered into an agreement at that time and had they acted
09:38:34 reasonably in their negotiations. In determining this, you
09:38:39 must assume that both parties believe the patent was valid
09:38:42 and infringed and that both parties were willing to enter
09:38:45 into an agreement. The reasonable royalty you determine
09:38:50 must be a royalty that would have resulted from the
09:38:53 hypothetical negotiation and not simply a royalty either
09:38:56 party would have preferred.

09:38:59 In determining the reasonable royalty, you may
09:39:01 consider the following nonexclusive list of factors, in

addition to any other evidence presented by the parties on the economic value of the patent:

1. The royalty, if any, received by UMN and Finch for the licensing of the asserted patents providing or intending to prove an established royalty rate.

2. The rates paid by Ferring to license other patents comparable to the asserted patents.

3. The nature and scope of the license as exclusive or nonexclusive or as restricted or nonrestricted in terms of its territory or with respect to whom the manufactured product may be sold.

4. UMN and Finch's established policy and program to maintain its right to exclude others from using the patented invention by not licensing others to use the invention or by granting licenses under special conditions to preserve that exclusivity.

5. The commercial relationship between the parties, such as whether or not they are competitors in the same territory, in the same line of business, or whether they are inventor and promotor.

6. The duration of the asserted patents and the term of the license.

7. The established profitability of the product made under the asserted patents, its commercial success, and its popularity.

8. The utility and advantages of a patented invention over the old modes or devices, if any, that had been used for achieving similar results.

9. The nature of the patented invention, the character of the commercial embodiment of it as owned and produced by or for UMN and Finch at the time of the hypothetical negotiation and the benefits to those who have used the invention.

10. The extent to which Ferring has made use of the invention and any evidence that showed the value of that use.

11. The portion of the profit or of the selling price that may be customary in a particular business or in comparable businesses to allow for the use of the invention or analogous inventions.

12. The portion of the realizable profits that should be credited to the invention as distinguished from non-patented elements, such as the manufacturing process, business risks, or significant features or improvements added by Ferring.

13. The opinion testimony of qualified experts.

14. The amount that a licensor, such as UMN and Finch, and a licensee, such as Ferring, would have agreed upon at the time the infringement began if both sides had been reasonably and voluntarily trying to reach an

agreement, that is, the amount which a prudent licensee who, as desired as a business proposition to obtain a license to manufacturer and sell a particular article embodying the patented invention, would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a patentee who was willing to grant a license.

15. Any other economic factor that a normally prudent businessperson would, under similar circumstances, take into consideration in negotiating the hypothetical license.

No one factor is dispositive and you can and should consider the evidence that has been presented to you in this case, as well as any other factors, which would have increased or decreased the royalty that Ferring would have been willing to pay and UMN and Finch would have been willing to accept acting as normally prudent business people.

10.4, Reasonable Royalty, Comparable Agreements.

Comparable license agreements are one factor that may inform your decision as to the proper amount and form of the reasonable royalty award. A license agreement need not be perfectly comparable to a hypothetical license that would be negotiated between the parties in order for you to consider it. However, if you choose to rely upon

09:43:20 evidence from any other license agreements, you must account
09:43:23 for economic and technological differences between those
09:43:27 licenses and the hypothetically negotiated license between
09:43:31 the parties.
09:43:34 10.5, Reasonable Royalty, Apportionment.
09:43:40 A damages award must reflect the portion of the
09:43:44 royalty attributable to the patented compositions or methods
09:43:47 in the asserted claims. In other words, your damages award
09:43:50 must reflect the value you find attributable to the asserted
09:43:54 claims. UMN and Finch must give evidence tending to
09:43:57 separate or apportion UMN and Finch's damages between the
09:44:01 patented features and the unpatented features and such
09:44:04 evidence must be reliable and tangible, not conjectural or
09:44:09 speculative.
09:44:11 You may award damages based only on royalties
09:44:14 that are directly attributable to the value of the patented
09:44:18 technology. You may not award damages based on a royalty
09:44:21 attributable to the unpatented features of the accused
09:44:25 product. UMN and Finch bear the burden to establish the
09:44:28 amounts directly attributable to the patented features.
09:44:34 11, Deliberations and Verdict.
09:44:37 11.1, Introduction.
09:44:40 I have completed my instructions on the law.
09:44:42 All the instructions I gave you previously about the rules
09:44:48 for deliberations still apply and you will have a copy of

them with you. I will remind you that once you start deliberating, do not talk to the jury officer or to me or to anyone else, except each other, about the case.

If you have any questions or messages, you must write them down on a piece of paper, sign them and then give them to the jury officer. The officer will give them to me and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take me some time to get back to you. Any questions or messages normally should be sent to me through your foreperson. One more thing about messages. Do not ever write down or tell anyone how you stand on your votes.

For example, do not write down or tell anyone that you are split 4 to 4 or 6 to 2 or whatever your vote happens to be. That should stay secret until you are finished.

11.2, Unanimous Verdict. Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, it is necessary that each juror agree to the verdict. Your verdict must be unanimous. It is your duty as jurors to consult with one another and to deliberate with a view towards reaching agreement, if you can do so consistent with your individual judgment. Each of you must decide the case for yourself, but do so only after an impartial consideration of the

09:46:22 evidence with your fellow jurors.

09:46:24 In the course of your deliberations, do not
09:46:27 hesitate to reexamine your own views and change your opinion
09:46:31 if convinced it is erroneous. But do not surrender your
09:46:35 honest conviction as to the weight or effect of evidence
09:46:40 solely because of the opinion of your fellow jurors or for
09:46:45 the purpose of returning a verdict.

09:46:47 Remember at all times that you are not
09:46:50 partisans, you are judges of the facts, your sole interest
09:46:52 is to seek the truth from the evidence in the case. A
09:46:55 verdict form has been prepared for you. The verdict form
09:46:58 asked you a series of questions about the parties'
09:47:02 contentions. You will take this form to the jury room and
09:47:05 when you have reached unanimous agreement as to your
09:47:10 verdict, you will have your foreperson fill in, date and
09:47:14 sign the form. You will then return to the courtroom and
09:47:19 your foreperson will give your verdict. Unless you are
09:47:22 directed otherwise in the verdict form, you must answer all
09:47:25 of the questions posed and you must all agree on each
09:47:29 answer.

09:47:29 Before I continue, may I please see counsel at
09:47:33 sidebar briefly.

09:47:38 (Sidebar discussion.)

09:48:10 THE COURT: So there were just a couple of
09:48:12 things I wanted to raise. The first was to find out from

09:48:15 the parties if there were any objections in the manner in
09:48:17 which I read the juror instructions?
09:48:20 MS. DURIE: No.
09:48:20 MR. DE VRIES: No, Your Honor.
09:48:21 THE COURT: The second was, as I was reading 7.3
09:48:24 out loud, I noticed that it talked about 7.3, the parties
09:48:30 edited it to take out instruction and just referred to
09:48:33 method because, of course, the only claim that is being
09:48:36 alleged to be infringed by DOE is a method, but it left in
09:48:40 the language about selling a method. That's not right in
09:48:43 the law, but thinking about it, I don't think it could
09:48:46 possibly affect anything in this case, because we tell the
09:48:50 jury that they're only looking at indirect infringement for
09:48:53 the method claims. Does everybody agree on that?
09:48:56 MS. DURIE: Yes.
09:48:56 MR. DE VRIES: Yes, Your Honor.
09:48:57 THE COURT: Okay. Great. The second thing I
09:48:59 wanted to ask you about is that we have been going for about
09:49:03 an hour and it would be preferable, I think, to everybody,
09:49:06 if we were able to roll through all the closing arguments
09:49:09 without a break in between. And so one possibility is to
09:49:12 give the jury their morning break right now.
09:49:17 MR. DE VRIES: That's no problem.
09:49:18 THE COURT: UMN and Finch, do you have a sense
09:49:20 of how long yours is going to be?

09:49:22 MR. DE VRIES: Yes, about an hour. We'd like to reserve 15 minutes for rebuttal, so one hour --

09:49:27 THE COURT: And 15.

09:49:28 MR. DE VRIES: Yes.

09:49:30 THE COURT: Do you want to resolve --

09:49:32 MS. DURIE: No, it's fine.

THE COURT: How long do you anticipate for closing?

09:49:34 MS. DURIE: It's probably about 90 minutes. Maybe a little longer.

09:49:35 THE COURT: Yeah, so I think it could be a little longer.

09:49:40 I want to get the case to them so they could deliberate over lunch. I don't want them to have lunch between the closings either.

09:49:48 All right. In light of that, I think we should do closings for UMN and Finch now, take the break and then --

09:49:56 MR. DE VRIES: Yes, Your Honor, that's no problem.

09:50:03 THE COURT: Okay, great.

09:50:06 (Sidebar discussion concluded.)

09:50:20 THE COURT: We'll now hear closing arguments.

09:50:20 MR. DE VRIES: And would the Court like a copy of my closing presentation?

09:50:23

09:50:26

09:50:26 THE COURT: No.

09:50:28 MR. DE VRIES: Okay. Thank you. I will just get started.

09:50:35 Good morning, ladies and gentlemen of the jury. I want to start where I started at the beginning of the week and that is to thank you all for your service on this jury. We know that this is a sacrifice for you all to have to take so much time out of your lives and on the behalf of the University of Minnesota and Finch and the whole team of lawyers that I'm just one member of, I'd like to say thank you.

09:51:02 We're almost to the time where the case is going to be with you for deliberations and the outcome of this case will be, is and always has been your decision.

09:51:15 I'd like to take some time to explain to you what we think the evidence that was presented to you in this trial showed and why we are confident that we have proven our case that Ferring Pharmaceuticals, the defendant in this case, has infringed the patents, that patent infringement was willful, the patents are valid and damages are owed.

09:51:43 And I'd like to start back with where I began my opening presentation and that is with what brings us here today.

09:51:53 Again, in November of 2022, the FDA announced the approval of REBYOTA. And a couple of months later, it

was launched to the market. And as I explained to you at opening, there was one thing that the FDA didn't know and that that was that REBYOTA was based on the University of Minnesota and our client's patented inventions.

And at the trial, you were able to meet some of the founders of Rebiotix and hear their testimony and one of the founders explained when asked:

"Did the University have any intellectual property that concerned you?"

"No."

"Why were you not concerned?" And the testimony was, "We didn't use any of it."

And I think the evidence very clearly showed that that is not true.

Now, I'm showing you an exhibit. It is PTX-266 and PTX-265. The reason I'm saying those numbers is, you'll have all of these exhibits back in the jury deliberation room and if you'd like to look at any of them, you can. This exhibit explains, as I've showed here, that RBX was derived from the Hamilton procedure. That's what Rebiotix said in its technical proposal in 2015 before this litigation was started.

And I would submit to you that it is very important to look to see what the parties were saying before the lawsuit as very important evidence of what happened.

09:53:46 And the Hamilton paper that's referred to, as you can see,
09:53:51 is Hamilton 2012. Hamilton 2012 was the seminal paper that
09:54:02 was authored by Dr. Khoruts and Dr. Sadowsky, the University
09:54:07 inventors who you heard testify in this case and has been
09:54:12 explained, I think, by multiple witnesses, including
09:54:15 Dr. Benson. This paper contains Example 4 from the '914
09:54:24 patent. So the paper that they admit that REBYOTA was
09:54:28 derived from contains Example 4 from the patent.
09:54:35 And it's not surprising that in a 2015 technical
09:54:40 document, Rebiotix admitted something that's different than
09:54:47 they're telling you now, and that's because the evidence
09:54:50 that you've seen and I'm going to quickly summarize it, is
09:54:54 very clear, that the people that were making and founding
09:55:00 Rebiotix were looking at information about the University's
09:55:06 invention, passing it amongst themselves and studying it for
09:55:12 years. So it's no surprise that in their technical
09:55:16 proposal, they admitted that REBYOTA is derived from
09:55:22 Hamilton, the University's patented invention. And you can
09:55:26 see that here in PTX-47.
09:55:30 These are the founders of Rebiotix. You'll
09:55:34 remember Mike Berman, you saw him on the stand testify. You
09:55:39 may recall, he was their first witness, we called him out of
09:55:43 order so he could get to another engagement, but he, along
09:55:46 with Lee Jones and someone named Erwin Kelen, were talking
09:55:52 in 2012, in this e-mail months and months after Rebiotix was

09:55:57 1 founded and they're talking about Hamilton 2012, the same
09:56:03 2 paper I'm talking about.
09:56:05 3 And it says, "See attached complete paper from
09:56:07 4 the U, very helpful to us." And when I asked Ms. Jones who
09:56:12 5 "us" means, you'll recall, she said, "us" means Rebiotix.
09:56:17 6 Taking information from the University and
09:56:21 7 sharing it amongst the people who founded Rebiotix had
09:56:25 8 actually started much earlier than what I just showed you
09:56:28 9 and I wanted to highlight that.
09:56:29 10 So again, Mr. Berman, who you saw testify as
09:56:34 11 their first witness, he is married to somebody named Judith
09:56:39 12 Berman, Dr. Berman, and as you heard at the time, she was a
09:56:44 13 professor at the University of Minnesota along with
09:56:46 14 Dr. Khoruts and Dr. Sadowsky. And Mr. Berman, as he
09:56:51 15 testified, was getting interested in this kind of a thing
09:56:57 16 and Dr. Berman sent Mike Berman some information in 2010.
09:57:02 17 So this is two years before the e-mail I just showed you.
09:57:07 18 And Dr. Berman tells Mike Berman about
09:57:12 19 Dr. Khoruts and Dr. Sadowsky and refers him to a link to an
09:57:18 20 abstract for a paper and that paper was written by
09:57:23 21 Dr. Khoruts about the technology that's at issue in this
09:57:27 22 case. And that flow of information from the University to
09:57:32 23 Mike Berman about the technology at issue in this case, it
09:57:37 24 continued. And so here is an example where Dr. Berman is
09:57:41 25 sending Mike Berman, in 2012, right after that e-mail where

09:57:47 Mike is looking at the 2012 Hamilton paper, some information
09:57:52 about a presentation that Dr. Khoruts was going to be
09:57:57 giving.
09:57:57 And you also saw that the other -- another one
09:58:03 of the Rebiotix cofounders, Lee Jones, was also circulating
09:58:08 within Rebiotix information about the University's patented
09:58:14 invention at issue in this case. So this is in September of
09:58:19 2011, several months after Rebiotix started. And Ms. Jones
09:58:24 is sending to Barbara Nelson, who is both a consultant and
09:58:28 the chief technology and commercialization officer for
09:58:32 Rebiotix at the time, a presentation. This presentation is
09:58:39 about intellectual property, including the patent that's at
09:58:43 issue in this case, the Dr. Khoruts and Sadowsky
09:58:46 presentation and patent.
09:58:49 And you may recall that Ms. Jones admitted that
09:58:52 she sent this to Dr. Nelson, not surprisingly because it
09:58:58 might be useful to her. And then I asked, "Are you denying
09:59:02 to the jury that you were sending these University materials
09:59:06 to Dr. Nelson in connection with the work she was doing
09:59:09 related to C. diff for MicrobEX," which was the original
09:59:14 name for Rebiotix, and Ms. Jones said, "No, I'm not denying
09:59:19 that." And that's a pretty critical moment, I think, in
09:59:24 this trial, I would respectfully submit.
09:59:28 And you'll recall that the way that Ms. Jones
09:59:31 obtained some of this information was because she was

working as a CEO-in-Residence at the Venture Center and she explained and agreed that she was there to assist the University. That was the role that she had in working with the Venture Center.

Fast-forward to about, a little under a year after Ms. Jones left the Venture Center. She's working with Mr. Berman and others at Rebiotix. As you can see in February of 2012, Ms. Jones is forwarding something to Ms. Guthertz. Ms. Guthertz was a consultant for Rebiotix at the time, and she's sending what she calls an earlier incarnation of one of the papers. And what she's forwarding is an e-mail from almost a year earlier from May of 2011 from Dr. Khoruts that she had received while at the Venture Center with a manuscript from Drs. Khoruts and Sadowsky on fecal microbiota transplantation.

There was additional information that was provided to the Rebiotix founders as well. You'll recall that Ms. Jones received the UMN patent application and also the invention disclosure document in April of 2011 while she was a CEO-in-Residence. And it's marked confidential only because it had not yet been published at the time. So when that document was received, it had this confidential mark on it, but eventually, it became public.

What we've learned in this litigation and I think you saw at the trial was this same patent application,

10:01:19 the one that led to Dr. Khoruts' patent was still in
10:01:24 Ferring's computers in 2022. I asked whether this number
10:01:30 indicates that this document, the same document, was
10:01:34 produced out of Ferring's files in this litigation. And
10:01:36 there's a page at the end that I showed Ms. Jones that's
10:01:40 called a metadata slip sheet. It provides some information
10:01:44 about the electronic record of the document. And what it
10:01:49 shows is that it was on a file path at the bottom that says,
10:01:53 "Lee Jones, U drive documents, Lee Jones documents, newco
10:02:00 ideas." And that was on Ferring's computers.
10:02:03 And the evidence showed that that wasn't the
10:02:07 only UMN document that was on Ferring's computer still in
10:02:12 2022. It also included Dr. Khoruts' and Sadowsky's
10:02:17 invention disclosure and that same patent presentation that
10:02:20 we had seen Dr. Nelson receive almost 10 years earlier.
10:02:25 And as you can see from PTX-423, which is
10:02:28 another one of the documents that we found on Ferring's
10:02:31 computers, newco ideas, that folder where these had been
10:02:37 stored at Ferring had a subfolder called MicrobEX, and as
10:02:42 Ms. Jones explained, MicrobEX is one of the names that had
10:02:47 been used for Rebiotix early in what occurred.
10:02:52 This is another really critical document because
10:02:57 here in PTX-170, you can see -- Mike Berman, again, their
10:03:05 first witness, Rebiotix's founder, acknowledging that the
10:03:08 founders of Rebiotix not only knew about the patent, the

University patent, they were actively studying it.

So Dr. Berman, professor at the University, she asked Mike Berman, "Do they," referring to Dr. Khoruts, "have a patent application in?" They're already thinking about -- that they had patent problems. This is in 2012.

And Mike Berman says, "I have not seen it. Lee has" -- that's Lee Jones, of course -- "and thought it was very sciencey." And so they're acknowledging in an e-mail that they're actually looking at, studying and talking about Mike Berman and Lee Jones, the patent application that led to the patent that's in this lawsuit.

And I think there's really no question that Rebiotix, that ultimately was acquired by Ferring, had its inspiration from the University of Minnesota. I asked Ms. Jones, "Is it true that Rebiotix got its original inspiration from the University of Minnesota?" The answer was yes. And the documents confirmed this. So this was a business plan about -- named Symbiome at the time. You'll remember the name of Rebiotix sort of kept changing.

Ms. Jones agreed that she's referred to Symbiome as a predecessor to Rebiotix. And the document explains that the company's founder was inspired by the works of Drs. Khoruts and Sadowsky and acknowledges that they created a simple solution to a terrible problem.

And there's no question that having known about

these patents and the issue and the information that they were seeing about the University's technology, that Ferring knew it had a problem.

So this is 2020. This is a few years before REBYOTA was even launched. This document is PTX-298, and one of the people working within Ferring says, "One additional point that Lee reminded me of is that use of the terminology highlighted below in yellow is important to avoid potential patent infringement issues." And so in 2020, Ms. Jones is telling -- talking with people in Ferring about potential patent infringement issues.

And there's no question that the founders of Rebiotix, Mike Berman, as you can see at the top, and then Lee Jones, they knew not only about Drs. Khoruts' and Sadowsky's patent, they knew about all of the patents that were going to be owned and licensed by my other client, Finch. This is from 2014. This is PTX-208.

And they're talking about CIPAC, which you'll remember was the name of the company that eventually became Finch and that CIPAC had some IP and it related to Dr. Tom Borody, who Lee Jones calls the pioneer of FMT. And in 2014, they talked about picking it up, picking up the IP that's at issue in this case, this intellectual property it refers to and includes in the patents. And then this is a really important document, because although they, I think in

this case, have claimed that they didn't really think there was a problem and maybe it wasn't an issue, when Ferring bought Rebiotix in 2018 from the shareholders, the parties included this provision in it that specifically talks about the patents in this case, and it says that the sellers of Rebiotix have to be obligated to split paying for the patents in this case because Ferring was so worried about them that it wasn't going to buy Rebiotix and face the risk of this lawsuit on its own.

Now, two things: One is that as you heard from Ms. Jones, the original sellers of Rebiotix, they actually reached an agreement with Ferring, so they're no longer on the hook here. They're sort of out of the picture at this point. But what I think this leaves no doubt about is that Ferring was worried. They knew there was a problem.

So what did they do? They bought the company anyway, they paid $175 million for Rebiotix, and then despite hearing all of these warnings and knowing everything they knew, in January of last year, they went ahead and started selling REBYOTA.

Why did they do it? The reason that so many people do things that aren't great. Money. And a lot of it. This is the sales forecast from August of 2022, where they anticipated revenue by 2031 of $2.1 billion and peak revenues of $300 million, and this comes out of a sales

10:08:55 forecast that the evidence showed they have never amended to
10:08:59 this day. And I'm going to come back to that.
10:09:02 Now, what about our clients, the University of
10:09:06 Minnesota and Finch? I think you've seen a lot of this. So
10:09:10 I can move through it, I think, relatively quickly.
10:09:14 Everyone agrees that C. diff is a huge problem when it
10:09:17 becomes recurrent, leads to death, leads to problems.
10:09:22 There's no question about that. And there's really no
10:09:25 question that Dr. Khoruts, who was profiled in the *New York*
10:09:28 *Times* as this technology was emerging is the key innovator,
10:09:33 along with Dr. Sadowsky, for the technology to address this.
10:09:37 You heard them describe it in detail. They came
10:09:40 up with an invention that could be used to transplant
10:09:45 healthy gut microbiomes in a way that was ready to use and
10:09:50 could be provided to many, many different patients to
10:09:55 restore their gut microbiome. And they were awarded a
10:10:00 patent for that work, as you know. That's why we're here.
10:10:04 And more than that, their work has led to super
10:10:09 significant benefits to humanity. This has been
10:10:14 Dr. Khoruts' life work, and it's really important. He has
10:10:18 personally treated a thousand people, but he's personally
10:10:22 worked on over a hundred thousand treatments for people.
10:10:24 And you saw those statistics about how many people can die
10:10:28 here. And so this isn't just about money, although money is
10:10:34 always important when you're talking about investment and

10:10:37 research. It's about saving lives.

10:10:41 The University of Minnesota, I want to be really
10:10:44 clear. We, they are a party to this litigation. The
10:10:48 University of Minnesota is here because of the values that
10:10:52 the University, a public University has that they want to
10:10:55 protect. Their values are research, education, service to
10:11:02 community and humanity, and the University licenses its
10:11:07 patents for societal impact and also for royalties because
10:11:11 it takes those royalties -- it's not a profit company -- and
10:11:14 it puts them back into research to create more of the kind
10:11:18 of research that Dr. Khoruts has created.

10:11:22 That brings us to Finch. Finch Therapeutics.
10:11:25 Finch Therapeutics did the right thing. It wanted to
10:11:29 develop a product based on the University's technology. And
10:11:33 it took a license from the University to do that. And it
10:11:37 continues to hold that license today. Why do I say it did
10:11:41 the right thing, because that's in huge contrast to Ferring
10:11:48 which did not get a license, did not ask for a license, did
10:11:51 not pay for a license even though -- you saw the evidence --
10:11:53 they knew full well that this was a major problem and they
10:11:57 went forward anyway.

10:11:59 As Dr. Khoruts explained, the University and
10:12:02 Finch, they have a partnership. That's how they view it.
10:12:06 And it's a partnership that started in 2012 at the infancy
10:12:11 of much of the work that was going to be done. And Finch

10:12:16 invested a tremendous amount of time, years, hundreds of
10:12:23 scientists, tens of millions of dollars, the number that
10:12:28 Mr. Burgess explained was $92.9 million they invested in
10:12:33 bringing the CP101 drug, the C. difficile drug to market.
10:12:39 What about Ferring? I was pretty startled by
10:12:42 this. Yesterday, their final witness was a damages expert
10:12:45 talking about how much money they should have to pay if you
10:12:48 find that they're liable for infringement. And what he
10:12:52 said, you might ask -- he was asked on his direct -- this
10:12:55 was not a cross-examination question -- how much did Ferring
10:12:59 invest in developing REBYOTA? I was not able to get a
10:13:03 precise answer. I wasn't able to get a complete number.
10:13:06 Of course, Ferring has the information about how
10:13:09 much they spent developing this drug. Ferring
10:13:14 Pharmaceuticals company has many drugs. And I think a fair
10:13:18 inference is it's obviously, for all the reasons that we're
10:13:24 here, less than the $92 million that Finch spent which
10:13:28 doesn't even account for what the University has invested.
10:13:31 And Finch also brought to the table those
10:13:34 Dr. Borody patents that we talked about. This is the same
10:13:38 e-mail that I referred to earlier, so I won't belabor it,
10:13:41 but they understood that those patents were really
10:13:45 important. Lee Jones refers to Tom Borody as the pioneer of
10:13:50 FMT, and she's referring very specifically to intellectual
10:13:54 property because it's important.

10:13:56 And the impact of the infringement on the
10:14:00 University and on Finch is real, and it's significant.
10:14:06 Dr. Khoruts explained the harm that Ferring's infringement
10:14:10 has had on the University. And Kevin Anderson did too. He
10:14:18 explained that they've lost out on the consideration for
10:14:22 what they would get from this litigation, and the
10:14:26 acknowledgment for their inventions that he explained is
10:14:29 very helpful to the University's licensing.
10:14:33 And then what about Finch? Finch spent, as
10:14:36 you've heard, $92 million. It was on the last trial before
10:14:41 FDA approval when it ran out of money. Now, we are not
10:14:45 saying that Ferring's infringement is the only reason that
10:14:50 Finch ran out of money. There's a number of different
10:14:53 factors that you have heard about. COVID was happening,
10:14:55 markets were in a particular place, but there is no question
10:14:58 that Ferring's launch of an infringing drug right before
10:15:03 Finch was hoping to get approval was a very detrimental
10:15:09 factor and ultimately, Finch had to shut down its drug
10:15:13 development program.
10:15:15 I think it's important to remember what their
10:15:19 witnesses said about what they did and didn't do to deal
10:15:22 with these issues. One is that Mike Berman, Lee Jones, they
10:15:28 both explained that there were no changes made to REBYOTA to
10:15:33 avoid infringing or in response to these patents. They
10:15:38 didn't make any changes. And they didn't make any payments.

10:15:42 They didn't offer to pay anything. That's what Kevin
10:15:46 Anderson said. That's what Mike Berman said. "I'm not
10:15:49 aware of Finch paying anything."
10:15:52 And, of course, as I thought yesterday, their
10:15:56 damages expert, Ferring's damages expert put it, he was
10:16:00 asked, "Rebiotix didn't end up taking a license?" And he
10:16:03 said, "That's why we're sitting here." And that is exactly
10:16:07 right. That is why we're sitting here. So at the beginning
10:16:11 of my opening statement, I said that we've heard a
10:16:14 hodgepodge of shifting excuses, and I wasn't entirely sure
10:16:19 which ones we were going to hear at trial so I want to walk
10:16:23 you through those.
10:16:24 Sorry, let me back up.
10:16:27 I'm going to start with "treat" and then I'm
10:16:31 going to come back to approximately .5. So treat, for this
10:16:36 whole case, going into this trial, their argument was that
10:16:39 they didn't infringe the '309 patent because they said that
10:16:43 REBYOTA didn't treat recurrence of C. diff. They said it
10:16:48 prevented recurrence of C. diff. You'll remember me saying
10:16:53 that. And we put on testimony at trial -- or I'm sorry -- a
10:16:57 transcript, which is in evidence, from their global clinical
10:17:01 operations head that used the word "treat." And then even
10:17:07 their technical expert, Dr. Johnson, was asked:
10:17:10 "And that's the point of REBYOTA, is to treat
10:17:12 C. diff, right?

10:17:13 "ANSWER: That's correct."

10:17:15 And so that -- what I characterize as a word
10:17:20 game, and I stand by that characterization, that defense
10:17:24 seems to have gone and is no longer here.

10:17:28 You'll remember I also explained that I
10:17:30 predicted that we'd hear an awful lot about somebody named
10:17:34 Hlavka. Never came, never provided any testimony, but we
10:17:40 got to hear some information about Mr. Hlavka from the other
10:17:44 witnesses.

10:17:45 So, Mike Berman, who you heard a lot from, he
10:17:49 explained the following, and I think this is really
10:17:51 important: On January 18th of 2010, Ed Hlavka had received,
10:18:00 as you can see here, an article that was written by
10:18:06 Drs. Khoruts and Sadowsky and he says it's some of the first
10:18:10 objective evidence for the mode of action for fecal
10:18:12 transplant and he filed his first patent application two
10:18:19 weeks later. Two weeks after he's talking to Drs. Khoruts
10:18:24 and Sadowsky about their work, he files a patent
10:18:28 application.

10:18:29 And as Mr. Berman admitted on cross-examination,
10:18:35 Hlavka had not performed any fecal transfers, he had not --
10:18:40 Mr. Berman wasn't aware of any lab research, of any clinical
10:18:45 ideas. He couldn't recall any ideas that Mr. Hlavka had
10:18:48 come up with and he couldn't think of any actual work that
10:18:53 Mr. Hlavka did to develop a process for treating stool for

10:18:56 purposes of FMT.

10:19:01 And when you get down to brass tacks with
10:19:04 patents, as Her Honor has instructed, you have to look at
10:19:08 the claims. The actual claims of the patents that are in
10:19:12 the case. And you may recall that I asked their expert, who
10:19:15 has said, well, I think the patent office got it wrong and I
10:19:18 think all of these claims are obvious, the Dr. Borody
10:19:22 patents. He was never talking about Dr. Khoruts' patents.

10:19:25 And I showed him, well, look, the claims say
10:19:31 antioxidant and its protection from exposure to air. And he
10:19:34 had to admit on cross-examination, Hlavka did not disclose
10:19:37 an antioxidant. Full stop, end of story.

10:19:40 There's one more claim, I'm not forgetting about
10:19:43 it. It's the one that talks about polyethylene glycol. You
10:19:46 probably remember that, it's a poison. And he had to admit
10:19:51 that what he was pointing to in this Hlavka patent
10:19:54 application, filed two weeks after Hlavka got Dr. Khoruts'
10:19:59 article, doesn't say polyethylene glycol. And I'll come
10:20:04 back to that, too.

10:20:06 So then we've got their last excuse that I had
10:20:10 predicted that they would come forward with, that's the
10:20:14 0.5 millimeter approximately. I'm going to address this in
10:20:17 some detail, but this is a document that came into evidence
10:20:21 at trial; and it's PTX-298, this is the potential patent
10:20:27 infringement one. Look at the sequence.

10:20:30 The beginning says the pore size is
10:20:35 0.5 millimeters, the same in the claim. Then it refers to
10:20:40 approximately 0.5 millimeters and that's the language where
10:20:46 he says that Lee reminded him it's important to use because
10:20:51 of potential patent infringement issues. And Courtney
10:20:55 Jones, who came to testify, she explained this very clearly
10:20:59 on the stand, that -- when asked what the pore size of the
10:21:02 filter bags is for REBYOTA, she says we documented it,
10:21:09 0.5 millimeters.
10:21:10 Now, there was a new argument that I'm somewhat
10:21:14 surprised that they made, but as I said, you know, couldn't
10:21:16 tell for sure what -- what would be argued, and that is that
10:21:20 they say for Dr. Khoruts' patent, that he didn't -- and he
10:21:23 and Dr. Sadowsky didn't put enough description of their work
10:21:27 in the patent. And the implication from their opening
10:21:30 was -- and perhaps, I don't know if they'll say it now or
10:21:34 not, but that they didn't actually do the work. They didn't
10:21:37 actually do the work. They also said that there was a
10:21:40 problem with a figure, that it was sort of blurry and it
10:21:43 should have been in color.
10:21:47 Drs. Khoruts and Sadowsky did the work. It
10:21:49 was -- they were asked -- originally, it was suggested they
10:21:52 had a single patient, right? But, no. If you look at the
10:21:55 patent, which you'll have, just look at it, there's an
10:21:58 Example 4, it refers to 43 consecutive patients and a

10:22:05 table -- tables of data from that, that work was done, no
10:22:09 one is making anything up, and the suggestion is, frankly,
10:22:11 offensive.
10:22:12 There are some other things that they've said
10:22:16 that are clearly not excuses for their infringement, but
10:22:20 I -- they've come up so often, I feel like I need to address
10:22:23 them.
10:22:24 One is OpenBiome. They talked about OpenBiome a
10:22:27 lot. There's even some questioning about whether OpenBiome
10:22:31 some years ago and it -- how it was approaching its
10:22:34 regulatory work.
10:22:35 OpenBiome is not a party to this case and that's
10:22:39 going to be a pretty important theme, I think, as you can
10:22:42 see some of these other excuses that they've made at trial.
10:22:46 It's a nonprofit company. James Burgess explained that. He
10:22:50 was one of the cofounders, he left and he joined Finch and
10:22:54 Finch is not associated with OpenBiome at this point. And
10:22:57 Lee Jones explained that, too. They're out there in a
10:23:00 nonprofit way trying to get this technology out into the
10:23:03 world and nothing about OpenBiome is at issue in this case.
10:23:06 You will not be asked any questions about that.
10:23:08 There's also been a repeated implication that
10:23:12 Finch is somehow at fault for Ferring Pharmaceutical's
10:23:19 infringement, that Finch could have done better, that they
10:23:22 were -- they wanted to -- they were dreaming big and they

10:23:26 tried to do a lot, and they wanted to -- you know, they had
10:23:29 flashy partnerships is how Ferring put it in the opening
10:23:34 statement and they were working on Crohn's disease and they
10:23:36 were working on autism things, and that they dreamed too big
10:23:40 and it didn't work out.
10:23:42 Well, a couple of things. One is Finch invested
10:23:45 a tremendous amount of time. It's an inaccurate picture to
10:23:49 try to paint Finch as a failure. Finch spent a tremendous
10:23:53 amount of money. But as Dr. Khoruts, I think, put it really
10:23:56 clearly, they were just one trial short when this all went
10:24:03 down. But more importantly, none of this is an excuse for
10:24:09 patent infringement, this does not mean you get to use the
10:24:12 University and Finch's patents for free. It doesn't work
10:24:15 that way.
10:24:16 Along the same lines of sort of excuses that
10:24:21 aren't really excuses, Ferring has tried to blame the
10:24:25 University or suggest that maybe nothing wrong happened
10:24:29 because Ferring -- I'm sorry -- the University didn't do
10:24:31 something earlier.
10:24:32 So you saw a lot of testimony that said -- that
10:24:37 referred to this concept, that the people at the University
10:24:41 were nice to the people at Rebiotix, congratulated them,
10:24:45 were happy for them. That's the normal thing to do. And
10:24:48 then there was a suggestion, this is what was said in
10:24:51 opening, this is not what you say to the burglar who broke

into your house.

A couple things about that that I think are really important. One is when did the evidence that you had the chance to see in this case come to light publicly? It was on Monday. The reason is that the files that we got from Ferring that were provided in this litigation, which was filed in December of 2021, so after that, and they're kept confidential until the trial, until everybody can see.

But more importantly, I think, this isn't a case about burglary or theft. In opening, that's how Ferring characterized what I had said. I actually never said any of those words at all because it's not a case about that. It's a case about patents and whether Ferring Pharmaceutical infringed patents.

Ms. Jones, when I asked her about that, she agreed that's what this case is about and she agreed, you can copy a patent even if it's public. This isn't about confidential versus not confidential. This is a patent case.

There was another one that I think maybe even kind of went one level -- kind of one rung down in relevancy and that was that the University is somehow out to assassinate the character of Lee Jones. That is absolutely false. And I'll submit to you that's an effort at misdirection. It's an effort to take the focus off who the

defendant in this case is, Ferring Pharmaceuticals; and Ms. Jones explained that. She's not a party to this litigation, Ferring is the party. They're the ones accused of patent infringement. She's not liable for that patent infringement, whether it's willful or not. This is a case about Ferring. And let's, you know, be real, if I can put it that way. Ms. Jones sounded the alarms to Ferring. She wasn't even there when they launched REBYOTA. Okay. And in 2020, she's talking about patent infringement issues. And you know what Ferring did, they just went ahead anyway. She was gone, everybody who was one of the founders was gone, and they started selling.

And this brings me to their final excuse. And that is that I think they've tried to suggest that, well, they haven't made a lot of money and I guess the implication is, well, even if we took it and even if we shouldn't have, you shouldn't really make us pay a lot. And they've never said that the product is a failure, but I -- I believe that that was the very strong implication. And it's absolutely not true.

There were -- this product launched last year, okay. The very first sales were in 2023 and I'm showing you the analysis that our damages expert showed of the real data of what they were selling. And was the launch a little bit below their initial estimates? Sure it was. But to the

10:28:11 extent that they're suggesting that something is wildly off
10:28:14 track, I wanted to show you with data that that was
10:28:17 absolutely not correct.
10:28:20 Take their actual sales between 2023 and 2024,
10:28:24 they increased 64%, if you just take the sales that we have
10:28:29 from this year for seven months and assume that they'll be
10:28:33 average for this year. And you'll recall that
10:28:37 Mr. Malackowski explained that, he explained that the sales
10:28:41 have been increasing by about 50% or so, a little more.
10:28:46 If you apply that same level of increase, look
10:28:49 at how quickly you get up to the numbers that are shown
10:28:52 here. By 2027, 53 million. 2028, 82 million. And so on.
10:29:01 And of course, this drug isn't a failure, that is exactly
10:29:04 why we're here.
10:29:06 And, you know, finally, before I want to take
10:29:09 you through the jury verdict form and share some comments
10:29:13 that I hope will be helpful in your deliberations. It
10:29:17 wasn't just the excuses that they've leveled. It's actually
10:29:20 kind of one step more and you heard Dr. Khoruts explain
10:29:24 this. In the months leading up to this trial, instead of
10:29:28 offering to pay for the patents or seeking permission to try
10:29:31 to get together, instead they threatened a public University
10:29:37 for patent infringement. That claim is not in this case.
10:29:40 It's not in any case. But look at -- look at that, he
10:29:46 described it as bullying, threatening. He had a clinical

10:29:50 program. They were basically sending jitters through the
10:29:54 institution. That's what happened instead of paying for the
10:29:58 patents.
10:29:59 So now I'd like to walk you through the jury
10:30:03 verdict that you're going to see. You're going to be asked
10:30:06 questions, infringement, willful infringement, validity and
10:30:10 damages. And I've talked about much of this, but I hope
10:30:13 that I can put this in a framework that will be helpful to
10:30:16 you.
10:30:17 There are three patents in this case, the
10:30:19 University patent on the left and the two Finch patents from
10:30:22 Dr. Borody on the right. As I predicted, there was no
10:30:26 dispute that they infringed the '080 patent. They brought
10:30:31 no expert to come and explain that they don't infringe it
10:30:35 and we did the opposite. And after we put on Dr. Stollman,
10:30:41 Dr. Benson, Dr. Park, they only challenged one of the parts
10:30:49 of the claim from the UMN patent and that's that
10:30:53 .5 millimeter sieve, capable of passing through.
10:30:58 Now, throughout this trial, you've heard a lot
10:31:01 about things that don't matter when it comes to
10:31:04 infringement. This was the opening slide and there was a
10:31:07 suggestion in the slide that Rebiotix or REBYOTA doesn't use
10:31:14 a blender, doesn't use four sieves, it doesn't do everything
10:31:18 in the same way as this one protocol that was provided, one
10:31:24 of the early examples from the University.

10:31:27 But that's not the analysis and Her Honor just
10:31:31 instructed against that very type of argument. She said the
10:31:35 relevant comparison for infringement is between Ferring's
10:31:37 product and the claims, not any product of UMN or Finch.
10:31:43 And so what they've, I think, most heavily relied on is a
10:31:48 legally improper argument and their expert, Dr. Johnson,
10:31:52 admitted it.
10:31:54 Do the claims require centrifuge? No.
10:31:58 Do the claims require metal sieves, multiple
10:32:03 sieves? No.
10:32:04 Do the claims require a blender or a Waring
10:32:08 blender? No.
10:32:09 How about a Stomacher? No.
10:32:14 And so all of that comparison is completely
10:32:18 irrelevant to what you're being asked to decide, which is
10:32:22 whether they infringe the claims in the case.
10:32:24 And so that brings us to the only issue, which
10:32:29 is: Is the REBYOTA extract capable of passing through a
10:32:35 0.5 millimeter sieve? And, again, this is probably one of
10:32:38 the examples where you have to most look at what did they
10:32:41 say before the litigation was filed because what does the
10:32:47 manufacturer say? It says 0.5 millimeters. It doesn't say
10:32:50 approximately, it says 0.5.
10:32:54 Dr. Johnson agreed it was important to be
10:32:56 precise. And of course, Rebiotix, when it's talking about

10:33:02 this to the FDA, do they use some of the wiggle language
10:33:06 that they use here? No. You don't get to get away with
10:33:10 that in the FDA. They say 500 micron pore size. It's down
10:33:14 at the micron level. That's .5 millimeter. They don't say
10:33:18 499 microns or gee, sometimes it's different. 500 microns,
10:33:23 .5 millimeters. That's what they told the FDA and everyone
10:33:28 knows that that is a critical importance.
10:33:34 They tried to suggest, that well, maybe those
10:33:37 pores get stretched out a little bit. Maybe that happens.
10:33:41 It doesn't. How do you know? Well, my colleague showed
10:33:48 Dr. Johnson what it looks like. And I think passed it
10:33:51 around to you all too when those pores get stretched out.
10:33:55 And you know what happens? They stay stretched out, they
10:33:59 don't go back, which I think is sort of what had been
10:34:02 suggested. And how do you know -- I'm sorry for the graphic
10:34:06 nature of this, but this is the test that our expert,
10:34:10 Dr. Benson did where he replicated the REBYOTA process and
10:34:15 you can see after that, the actual process that's used, the
10:34:22 pore sizes are the same, there's no change. And so the
10:34:24 suggestion that well, maybe they stretched out, is not
10:34:30 right.
10:34:30 So what did they do? They brought an expert to
10:34:33 this trial that they hired to do a test. And he showed
10:34:39 you -- and I want to be really clear about this, he did a
10:34:43 test right here. It got put away before we were even

10:34:46 allowed to ask him about it. And he used prunes, okay. He
10:34:50 admitted this but I want to be really clear. That is not
10:34:54 REBYOTA. And what he showed you is nothing at all like what
10:34:57 his test looked like when he did REBYOTA.
10:35:01 And why do you think he used prunes? I mean, I
10:35:04 guess we'll leave it to you to decide but just that is not
10:35:08 REBYOTA and whatever he showed you is not what's going on in
10:35:11 this case. What he -- what he did, though, look at the
10:35:18 test, he used these, like, metal .5 millimeter sieves.
10:35:23 Pretty small and you heard that the surface area on those
10:35:26 things imposes some pressure on the particles and then he
10:35:30 didn't use a Stomacher bag or Stomacher and a bag that they
10:35:34 actually do in REBYOTA, he sort of put it in that thing and
10:35:37 I think he said he sort of moved it around gently.
10:35:42 But this is critical, the claims says capable of
10:35:45 passing through a 0.5 millimeter sieve. Here, REBYOTA
10:35:50 obviously, because it's passed through these .5 millimeter
10:35:55 pores. What Dr. Johnson said is, he understands what this
10:35:59 claims means, that you could have minimal particles that are
10:36:01 left on the surface, okay, that's what he said. That's not
10:36:04 our expert, that's what Dr. Johnson said. Our expert
10:36:07 agreed, you could have minimal particles.
10:36:12 Even with the metal sieves and the not using the
10:36:14 Stomacher and sort of swirling it around gently, what did he
10:36:18 show? Well, he said that there was some amount of REBYOTA

10:36:22 that was left on the sieve in his test, okay. He's already
10:36:29 explained that this claim allows for having a minimal amount
10:36:33 of particles on the sieve. So we're done. But I just
10:36:37 wanted to highlight this because it came up and to me, it
10:36:41 was very important. There are tens of millions of particles
10:36:47 in the REBYOTA bag and what he's showing there on the right,
10:36:52 that he said, oh, well, that was sort of left on top of the
10:36:56 little metal sieve I used, is absolutely minimal in
10:36:59 comparison to the tens of millions of particles in the bag.
10:37:02 So even under his experiment, we're done. There's
10:37:05 infringement.
10:37:07 And... but even that picture I just showed you
10:37:09 is actually unfair against us, because it doesn't show what
10:37:14 really happened next. And that is, he washed those
10:37:18 particles that were there and I think he tried to suggest on
10:37:23 the stand that maybe he didn't wash all of them, but my
10:37:27 colleague had to point out that when he described in his
10:37:30 report, he said, any particles were then recovered, "any,"
10:37:36 that's what he said before the trial. And you can see,
10:37:39 there are virtually none of them. You know, minimal at
10:37:45 best.
10:37:47 And I think this, though, is also equally
10:37:52 important. And that is that Dr. Johnson is not here to say
10:37:57 that because you saw some minimal number of particles that
10:38:01 were left on the sieve in his experiment that didn't even

10:38:04 replicate what REBYOTA does, that that matters. In fact, he
10:38:07 definitively does not have that opinion. He says, "I can't
10:38:13 say anything about the efficacy of that product after the
10:38:18 particles are removed." So he showed, "Oh, look, here's a
10:38:21 few minimal particles that are left and I can't even tell
10:38:24 you if it matters."
10:38:26 Now, why, in his experiment may there have been
10:38:29 some particles left on the sieve when it made it through the
10:38:32 .5 millimeter pores to begin with, right?
10:38:36 Why is that?
10:38:39 My colleague walked him through it but it's
10:38:43 because when you take a look at the particles that he
10:38:45 actually was pulling off and then looking at under a
10:38:48 microscope, that they have different shapes. I think
10:38:51 everybody agrees about that. And when you do it the way
10:38:54 that he did, they can clump together, they can get in a
10:38:59 place that they're not at when they're in a solution, right,
10:39:02 when the particles are separated and in water, which is how
10:39:06 it's actually done in REBYOTA.
10:39:08 And so when you've got certain sizes and some of
10:39:10 them clump together, then there are circumstances where a
10:39:16 couple of these particles, all of which are capable of going
10:39:20 through a .5 millimeters sieve might not go through on a
10:39:24 particular time. And at first, I think before he understood
10:39:31 where this was going, Dr. Johnson admitted that. I don't

10:39:36 think he kind of fully appreciated where this was going to
10:39:40 land, and so he said, my colleague asked, "This particle is
10:39:43 capable of passing through this sieve, right?" He showed
10:39:47 right here, he put it down and up. And Dr. Johnson said,
"Yes."

10:39:51 And then, though, it was sort of the end of the
10:39:53 demonstration, he said, "You'd agree that every single one
10:39:57 of these particles is capable of passing through the sieve?"
10:39:59 And then he changed his testimony and he said, "No."

10:40:02 As I keep saying, sieving is a single pass, and
10:40:05 he's sort of suggesting something pretty simple and wrong,
10:40:11 and that is that for something to be capable of passing
10:40:14 through a sieve, it has to do it every single time on every
10:40:19 pass. That is the opposite of what the language capable of
10:40:23 means and is obviously wrong.

10:40:26 And so for these reasons, the UMN patent is
10:40:29 clearly infringed and we think, as I'll show you in a
10:40:33 moment, that the evidence supports you checking "yes" for
10:40:38 infringement, literally.

10:40:39 But there's something more that you heard about
10:40:42 and I want to touch on it briefly. That's the doctrine of
10:40:46 equivalents. And so the law says, even if someone -- even
10:40:50 if something is not exactly the same as in the claims, but
10:40:55 the differences are insubstantial or -- and I'm
10:41:02 paraphrasing, you've been read, the whole amount would have

substantially the same function, work in substantially the same way and achieve substantially the same result, then there's infringement anyway.

And I think, as I've already shown, it's crystal clear from Dr. Johnson's testimony where he admitted, he doesn't know if this impacts the efficacy of the product, does it matter that there's some minimal particles out here? And so the super small number of particles and the very small size of those particles, there's no substantial difference. And you've heard extensive explanation about that from our expert, Dr. Benson, who explained why that is.

And Dr. Johnson, you may remember in his direct testimony, he didn't say anything about this issue, he didn't mention the doctrine of equivalents or those legal tests that I talked about, not even once. And so on the very last question of the very last part of his redirect so they get to come up again, he was asked, "Do you consider the strainer bag to be equivalent?" And he said "No," with no explanation.

But what he missed was any explanation that any distinction, we don't think there is one, that between what they do and what's in the claim matters and he's affirmatively said it does not.

And then finally on this point, you know, I said this at the beginning and I think it feels even more true by

10:42:34 the end of the week. This is another word game. It's a .5
10:42:43 millimeter pore that they use. Putting in the word
10:42:46 "approximately" is very obviously an attempt to avoid paying
10:42:49 the University for its patents. And it's not right under
10:42:53 the law for all of the reasons I explained and we would
10:42:56 respectfully submit -- you will be the judges, you will
10:42:59 decide what you think the evidence shows but we submit that
10:43:02 the evidence is very clear.

10:43:04 The only other non-infringement argument that
10:43:07 they offered didn't apply to the '080 patent, the first of
10:43:13 the Finch patents, it did apply to the second of the Finch
10:43:16 patents so that's the '309. After Dr. Stollman, Benson and
10:43:22 Park testified, they didn't challenge any of the limitations
10:43:25 in any of the claims except for the one in yellow, which is
10:43:28 whether the bacteria are separated from rough particulate
10:43:32 matter.

10:43:32 Again, you've seen this before, but this is that
10:43:36 somewhat unpleasant or very unpleasant picture. It's clear
10:43:43 that the bacteria that are in the REBYOTA mixture are
10:43:46 separated from rough particulate matter. How do you know?

10:43:50 Well, that's exactly what Dr. Benson's
10:43:55 experiment shows, that it's separated from the rough
10:43:58 particulate matter and Dr. Johnson agreed that what was
10:44:02 separated was rough particulate matter. And the reality is
10:44:09 that you have to look at what the Court said about what that

10:44:13 term means. And what Her Honor explained, is that this
10:44:18 claim term, when it refers to rough particulate matter,
10:44:21 refers to rough macroscopic nonliving matter. That's what
10:44:27 you see on the left inside the bag that REBYOTA uses. There
10:44:32 is no rough macroscopic nonliving matter on the right.
10:44:37 And how do you know? Well, he had to use a
10:44:42 magnifier to even look to see what he was talking about
10:44:47 here, a magnification of 40 times. And so I think there's
10:44:51 no real question that in REBYOTA that liquid that goes
10:44:54 through the strainer bag and ends up in the enema bag, has
10:44:58 been separated from rough particulate matter. So for that
10:45:02 reason, we believe -- and again, this is your choice, that
10:45:07 you'll be asked in Question 1, did we prove by a
10:45:11 preponderance of the evidence that all of these claims, the
10:45:16 University claim is first, the '914, then the '309 patent
10:45:20 and then the '080 patent. The '080 is the one where they
10:45:25 have no non-infringement arguments. And we would
10:45:28 respectfully submit that we believe the evidence supports
10:45:31 checking "yes" for all of those.
10:45:34 There's a Question 2 and the instructions will
10:45:37 tell you, you don't have to answer this question if you've
10:45:42 already checked "yes" to infringement for the UMN patent on
10:45:46 the earlier question. But if you don't, then you'll be
10:45:52 asked whether alternatively, we approved that that claim of
10:45:57 the University patent is infringed under the doctrine of

10:46:01 equivalents. And I think for all the reasons that I
10:46:04 mentioned, if you're at that question, the answer is clearly
10:46:07 "yes."
10:46:11 The next question -- it will be Question 3, will
10:46:14 be, did they willfully infringe, did Ferring
10:46:16 Pharmaceuticals, not someone else, did Ferring
10:46:19 Pharmaceuticals willfully infringe? You were given some
10:46:22 instructions from the Court about what that means and you
10:46:25 should remember and look at all of them. One of the things
10:46:28 they referred to is deliberate or reckless disregard of
10:46:32 UMN's patent rights and I've talked a lot about this, so
10:46:35 I'll be brief.
10:46:36 Clearly, they have. They've admitted that they
10:46:40 knew about the patents as of their issuance. They knew
10:46:44 about the applications before. They reviewed the patents,
10:46:48 including the ones that list Dr. Khoruts, you saw the
10:46:52 e-mails where they are talking about the patent application.
10:46:56 Mr. Berman admitted that Rebiotix was aware of
10:47:00 the Finch and University of Minnesota patents while it was
10:47:03 developing its products. And then as I said before,
10:47:07 Ms. Jones would sound the alarm within Ferring, before she
10:47:11 left, that there were patent infringement issues. Ferring
10:47:15 knew, that's why they put this provision in the merger
10:47:19 agreement as part of the deal.
10:47:22 And so for all of those reasons, we submit to

you that the evidence is very clear, that the infringement here was willful. And if you agree with us, then on a per-patent basis, you don't have claims on this one, we would suggest that the appropriate answer is to check "yes" for all three patents.

Okay. Almost done. They have raised something called validity defenses. They say the patent office screwed up and that all of the patents in this case are invalid. And you heard this from Your Honor but I'd like to pause for a moment to emphasize this. They bear a different burden of proof than we do in our case to prove this defense. It's called clear and convincing evidence as -- and as Her Honor explained, that means that Ferring Pharmaceuticals in this defense has a higher degree of persuasion that is necessary to meet the preponderance of the evidence standard that applies to our claims. So they have two arguments, they're different by patent and I want to go through them.

The first is they argue obviousness. And I'm going to paraphrase. You've heard all of this, but you have been cautioned that when you're thinking about whether a patent that was invented 10 years ago is obvious or not, it's really important -- well, what it specifically says is you must avoid using hindsight. That is, you should not consider what is known today or what was learned from the

10:49:07 teachings of the asserted patents. You have to put yourself
10:49:10 back in time to decide if these patents are obvious.
10:49:15 And as I previewed at the beginning of this
10:49:19 case, this argument does not apply to the University
10:49:23 patents. They concede that the University patents were new,
10:49:28 that they were not obvious, and they are not going to ask
10:49:31 you to decide otherwise. And I'm not surprised.
10:49:34 They are going to ask you to decide -- you heard
10:49:38 me questioning Wednesday afternoon, I was questioning
10:49:43 Dr. Britton, and he said in a pretty truncated way that he
10:49:45 looked at the patents and Hlavka and he thought that it was
10:49:49 probably -- and he thought it was obvious and said it was
10:49:52 invalid, said he thought it was obvious. Now, as I asked
10:49:57 him and he agreed, the same Hlavka that they're saying
10:50:03 renders them obvious, the Patent Office considered that
10:50:07 reference. They showed you parts where they're talking --
10:50:10 where the Patent Office is talking about Hlavka, and they
10:50:15 issued the patent anyway. And the opinion is that the
10:50:19 Patent Office got it wrong for four different claims across
10:50:24 two different patents that issued three years apart.
10:50:27 And we would submit that that's just not
10:50:30 plausible. But more than that, you have to look at the
10:50:34 claims again. And the claims that are at issue in this case
10:50:37 require antioxidants. Dr. Britton admitted that they
10:50:41 didn't -- that Hlavka didn't have an antioxidant or disclose

10:50:49 one. And I asked him if he had any other prior art
10:50:53 reference that talked about it that he showed you all, and
10:50:55 he said no. He didn't show any of those either. So he
10:50:59 showed you no prior art references that talk about
10:51:01 antioxidants. He just asked you to take it on faith that he
10:51:03 thinks it would have been obvious to just put in an
10:51:06 antioxidant even though he showed you no document that
10:51:08 actually said that.
10:51:11 And the same is true for exposed to air. He
10:51:13 actually didn't even try to explain how it was that that
10:51:16 part was shown by Hlavka, and he talked instead about a
10:51:20 sealed container, so he didn't even try there.
10:51:23 Now, what about PEG? That's the last one of the
10:51:32 claims that requires polyethylene glycol. And a couple of
10:51:36 things, when Hlavka talks about that word "glycol," that is
10:51:41 not the same as polyethylene glycol. There are hundreds of
10:51:46 glycols, and polyethylene glycol is a very specific one and
10:51:49 it is not disclosed in Hlavka. And the experts agree about
10:51:54 that. It's also a poison, so the idea of putting a poison
10:52:00 into something that could be used with the human body is
10:52:06 something that would only be undertaken in the most careful
10:52:09 of circumstances.
10:52:10 And then this is so critical, and you've got to
10:52:13 think about this when they're arguing that the claims are
10:52:17 obvious. Years later, Rebiotix in PTX-979, told the Patent

10:52:24 Office that polyethylene glycol would not be obvious to
10:52:29 combine as a substance that functions as a laxative to a
10:52:36 microbiota restoration therapy composition. They made
10:52:39 literally the opposite argument that they're making here.
10:52:44 You also have to, as you've heard, consider real
10:52:47 world factors. There was evidence of copying, and,
10:52:52 importantly, what they were copying was the University
10:52:56 patent, not Hlavka. And, of course, there was evidence of
10:53:02 licensing, that there was licensing that Finch entered into
10:53:05 for these same patents and why would someone pay for a
10:53:08 patent if it was obvious. And so we would respectfully
10:53:13 submit on question 4 that the answer to all four questions
10:53:16 is no.
10:53:19 That brings us to the written description
10:53:21 argument, the suggestion that Dr. Khoruts and Sadowsky
10:53:25 didn't actually invent what they say that they invented.
10:53:29 I've shown you before that what Ferring said in opening
10:53:32 statement is it's just one patent, and there's a figure that
10:53:36 nobody can read. But it wasn't just one patent -- or
10:53:41 patient. As Dr. Khoruts explained, there were 43 patients.
10:53:45 They actually performed this treatment on them, they
10:53:48 actually collected data and they actually put the data into
10:53:53 the patent.
10:53:53 And so then they say, "Well, the patent has this
10:53:56 figure, and you can't read it." They're only talking about

10:53:59 one of multiple figures and tables of data in the patent.
10:54:03 You'll see the instructions said you don't even need
10:54:06 examples in the patent. But we include -- you know, the
10:54:07 patentee included them anyway. Dr. Khoruts could read it
10:54:11 especially when you look at the text that accompanies the
10:54:14 patent. And Dr. Sadowsky explained that they had determined
10:54:19 that these changes in the microbiota were occurring and that
10:54:25 they were seeing that in their patients.
10:54:30 So they had an expert, Dr. Treangen. He came up
10:54:35 and he said that he couldn't read the figure very well. And
10:54:40 one of his complaints was it was black and white, but we
10:54:45 pointed out in the Patent Office, you use black and white
10:54:48 and it's not typical to use color in a patent.
10:54:52 Dr. Treangen, as we showed also, he uses the
10:54:55 very same kind of figures, and as you can see from just
10:54:59 looking, his figures are no more readable or not readable
10:55:04 than the figure in the patent, so it's obviously a double
10:55:07 standard. But more importantly, because what is this
10:55:10 defense really about? It's an accusation that Dr. Khoruts
10:55:14 and Dr. Sadowsky didn't invent what they claimed to have
10:55:18 invented, and that is false.
10:55:23 And even Dr. Treangen, who they had hired as a
10:55:26 consultant in this case, he couldn't say otherwise. He
10:55:29 said, "I did not claim anyone did not do the work." And for
10:55:32 the kinds of figures he was complaining about, he admitted,

10:55:36 "They're standard. We present them all the time." And when
10:55:40 shown the exact figure that they're complaining about in the
10:55:44 patent, he said, "They're -- to create a figure like that,
10:55:47 they are based on underlying tables of data and numbers."
10:55:51 Okay. No one thinks that Dr. Khoruts and Sadowsky have
10:55:57 pulled a -- have faked this. It is simply not true, and
10:56:01 even their expert doesn't say otherwise.
10:56:06 The verdict form is going to also ask you about
10:56:09 the '080 patent. I didn't hear any of their experts talk
10:56:13 about the '080 patent and written description at all. And
10:56:17 the '080 patent contains tons and tons of disclosures about
10:56:22 stabilizing agents and lots of different things, and they
10:56:26 have not presented any evidence, let alone clear and
10:56:28 convincing evidence, that the '080 patent is invalid. And
10:56:32 so we would suggest that for question 5, the answer to the
10:56:39 questions is no, that they have not proven by clear and
10:56:43 convincing evidence invalidity based on written description.
10:56:47 Last question, damages. So the experts are
10:56:53 looking at some license agreements. One of them was between
10:56:57 UMN and Finch that started 10 years ago before Finch
10:57:01 invested $92 million and ten years of efforts and the
10:57:05 University said, "We're here to stand behind Finch." Their
10:57:10 expert says that that agreement is a lot more relevant than
10:57:15 the Nestlé agreement. We think that's wrong for a number of
10:57:18 reasons.

10:57:19 One, the agreement between Finch and the
10:57:21 University is clearly -- they're partnering together to go
10:57:24 invest a lot of money to develop a product. And the
10:57:27 hypothetical negotiation here is, as you've heard, after
10:57:30 they've already received approval and they're two months
10:57:33 away from selling a product. They've already made the
10:57:36 investment. So there's a completely different type of
10:57:39 license.
10:57:39 And that Nestlé license was at almost exactly
10:57:43 the same time period as that hypothetical negotiation. For
10:57:48 a recurrent C. difficile product, it is the closest in time,
10:57:53 and it is the closest to the way that this kind of
10:57:56 negotiation would go -- where Finch, on the verge of getting
10:58:00 to sell its own product, is licensing its patent rights to a
10:58:04 primary competitor. Both of these licenses include upfront
10:58:09 payments and, interestingly, even the one that they're
10:58:14 relying on. Yet, they still don't include an upfront
10:58:17 payment.
10:58:18 And the evidence is really clear that in this
10:58:21 technology space, upfront payments are included all the
10:58:24 time. 75% in one of the reports that Mr. Kidder talked
10:58:28 about did. You saw this slide. The hypothetical
10:58:33 negotiation here is actually around group 3, right before
10:58:38 precommercialization. And you look at the maximum in this
10:58:43 study was 650 million and the median was 12 million. And so

upfront payments are here. They have not given you another number, a different number. They didn't provide one.

Mr. Malackowski did. He took the 175 million. He made a number of deductions to account for a number of things that he explained, and that's how he got to 50 million.

What about the percentage royalty? Mr. Malackowski said 30%. He started with the Nestlé agreement that had a 50% royalty. You probably remember because it was just yesterday. Their expert said, "Well, that's not a royalty rate." That is 100% false. If you look at the license, which is PTX-366 -- you can go look at it yourself -- what it says is that it is a royalty of 50%. I've shown it right there. And that's where they're at to try to avoid this evidence.

And when they do their reasonable check, they omit this, they don't put it on as a result of that argument. They show a bunch of other agreements instead, but each of those agreements is totally different. There was nonprofit. There was a partnership. In one case, it had $350 million of milestones that they're just ignoring. So that's wrong.

And so you will be asked to determine if you've answered the questions before in a way that would lead you to this question, what damages should be. We respectfully

11:00:18 submit that the running royalty should be 4.43 million.
11:00:21 That's 30% of their sales and an upfront payment of $50
11:00:27 million.
11:00:27 Thank you. I'll have a chance to come back and
11:00:30 very briefly talk to you at the end. Thank you.
11:00:33 THE COURT: Thank you very much. Ladies and
11:00:35 gentlemen, we'll take our morning break right now. We'll be
11:00:38 back at 11:15.
11:01:12 (Jury exits.)
11:01:12 MS. DURIE: Your Honor, there is one issue I
11:01:14 would like to raise with the Court with respect to the
11:01:17 closing argument. We just heard an argument with respect to
11:01:21 the obviousness of the Borody patents, that there was
11:01:23 evidence of secondary considerations of copying that was
11:01:26 pertinent to the obviousness of those patents. That is, I
11:01:30 think, contrary to the Court's instructions, which
11:01:36 provide -- and this is in Instruction 9.5 as read to the
11:01:39 jury -- that the factors include whether others copied the
11:01:43 claimed invention of the asserted claims of the '309 and
11:01:47 '080 patents, not whether there has been copying of an
11:01:51 entirely different patent.
11:01:54 And so we would request a curative instruction
11:01:56 on that point because there is no evidence of copying in the
11:02:02 record with respect to the '309 and '080 patents, and the
11:02:07 suggestion that the jury could rely on evidence of copying

11:02:10 with respect to the University of Minnesota patent is
11:02:14 legally erroneous.
11:02:16 THE COURT: All right. Why don't you meet and
11:02:17 confer about that. We'll take our break, and we'll hear
11:02:20 from the parties.
11:02:23 MS. DURIE: All right. Thank you.
11:02:25 COURT CLERK: All rise.
11:15:50 (A brief recess was taken.)
11:20:20 COURT CLERK: All rise.
11:20:26 THE COURT: All right. Please be seated.
11:20:30 MS. DURIE: Thank you, Your Honor. We did meet
11:20:33 and confer. The plaintiffs' view is that they were
11:20:38 arguing -- and I will let them speak on this if they want
11:20:42 to -- but that they were endeavoring to argue with respect
11:20:47 to the evidence of Borody copying and that the reference to
11:20:51 the Hamilton paper was to make the argument that we were not
11:20:54 copying Hlavka. I'm not sure that I follow that. I did not
11:21:00 write down precisely that was said, but I will say that the
11:21:06 folks on my side of the table saw what was put up with
11:21:10 respect to an e-mail that purports to be about copying the
11:21:14 Hamilton paper and heard it presented that way.
11:21:17 Our request -- and we discussed this -- was for
11:21:20 an instruction that simply would say, "Evidence of any
11:21:23 copying of the University of Minnesota patent is not
11:21:27 relevant to the obviousness of the Borody patents." The

request from Finch's position is that I can argue it with reference to the jury instruction. Obviously, I can. I do think their argument was inconsistent with the jury instruction.

I do think the curative instruction would be appropriate. I am fine with proceeding with my closing at this point and taking the issue up at the end. And I'm happy to sort of see how that goes. But I do have a concern that what was presented is not consistent with the law.

THE COURT: All right. Let's proceed with how you propose. We have some access to what was said.

MS. DURIE: I thought that that -- that we --

THE COURT: And so I don't think it came across the way that you might be worried, but I understand the concern and we'll review that and we'll reserve and decide after your closing.

MS. DURIE: That's perfect.

MR. DE VRIES: I would just like to note I disagree with the characterization. I'm happy to describe that whenever Your Honor would like.

THE COURT: All right. Thank you.

Are we ready?

MS. DURIE: Yes.

(Jury enters.)

THE COURT: Welcome back. Please be seated.

11:23:32 And now, we'll hear closings from Ferring.

11:23:35 MS. DURIE: Thank you, Your Honor.

11:23:37 And, ladies and gentlemen, good morning.

11:23:39 So as we just heard, this is a patent case and
11:23:44 so I want to start by talking about patents because in a
11:23:51 patent case, one of the things that's really important is
11:23:55 who was first. And this is an unusual patent case in some
11:24:01 ways because I think the evidence on that point is not in
11:24:05 dispute and the evidence on that point is that with respect
11:24:10 to the invention at issue in this case, which is to say,
11:24:17 this stool bank concept in Mr. Borody's patents, we were
11:24:25 first.

11:24:27 You've heard now about the Hlavka patent, which
11:24:32 we filed for on February 1st of 2010. And there's no
11:24:37 dispute that that's before any of the other patents that are
11:24:40 at issue. You will have a copy of the exhibit, as counsel
11:24:46 said. And I've tried to write in pretty big numbers, the
11:24:51 trial exhibit numbers, so that if you want to take notes,
11:24:54 you can write that down.

11:24:55 The Hlavka packet application is 3350, and if
11:25:00 you look through it, you'll see that what he was talking
11:25:03 about was this bacteriotherapy bank. Now, as you've all
11:25:10 heard, FMT, fecal transplants, were old. Nobody was going
11:25:15 to get a patent on the basis of how to do FMT in 2010 or in
11:25:22 2011 because that had been done for a long time. But the

11:25:26 idea here was how do we take this old process and turn it
11:25:33 into something that can be made into an FDA-regulated
11:25:39 commercial thing. That's what Mr. Hlavka's patent was
11:25:46 about.
11:25:46 Now, you heard Dr. Khoruts say when asked if
11:25:52 someone were to say that Mr. Hlavka invented standardized
11:25:56 FMT treatments, what would you say in response? And his
11:26:00 answer was that's ridiculous. But the patent office did not
11:26:04 agree with that assessment because the patent office issued
11:26:09 a patent, more than one patent, based on that February 1,
11:26:16 2010 application.
11:26:19 This is the Hlavka '208 patent, it's in evidence
11:26:23 at 3680, and you'll see it talks about a lot of the concepts
11:26:29 that you've heard about over the course of this trial, about
11:26:33 cryoprotectants and filtering and glycol and having a
11:26:37 storage bank and using an enema because those were all
11:26:42 concepts that he was working on back in 2009, in thinking
11:26:48 about how do we take this old technology and turn it into a
11:26:54 product.
11:26:55 Now, back in the day, Dr. Khoruts and
11:27:01 Dr. Sadowsky, I think, agreed that we were the first with
11:27:04 respect to these ideas. And one thing that I agree with
11:27:09 Finch's counsel on is that you should really look carefully
11:27:13 at what people said back then, right, not just what people
11:27:17 are saying today.

11:27:18 And back then, in May of 2012, when Dr. Khoruts and Dr. Borody and Dr. Sadowsky first learned about what REBYOTA was doing, this was actually when they first heard about some of Rebiotix's success, they said, "I believe these are the people from MicrobEX, they're certainly familiar with our work, although I believe they were thinking about these matters before ever meeting us."

That's what Dr. Khoruts said, that's what Dr. Sadowsky said back in the day, as well, and that's absolutely correct.

And, in fact, in 2013, when Debra Peattie, remember she was the person associated with NuQure from whom they -- with whom they originally entered into an agreement. When she raised a concern about this Hlavka patent and says it has a priority date of 1 February 2010, she said, one, you should start compiling records that document that you and Mike were first to invent. And I will note, you have not seen any records that they made these inventions before February 1, 2010.

And two, as you think about interactions with Lee Jones, it's worth focusing on what happened in 2009 that could have culminated in the filing on 1 February 2010. And of course, you all know, there were no interactions with Lee Jones in 2009 because she didn't start talking to folks at the University about this until March of 2011.

11:29:03 Now, what was going on back in 2009? What was
11:29:07 going on back in 2009 is that Mr. Hlavka and Mr. Berman were
11:29:11 working on this idea and that resulted in this business plan
11:29:15 that was presented to their board on January 14th of 2010.
11:29:19 And it has a lot of -- again, a lot of these concepts we've
11:29:24 been talking about -- an enema, having a healthy stool bank,
11:29:28 freezing the stool so that you would be able to preserve it
11:29:31 in that bank.
11:29:34 Now, on January 18th of 2010, Mr. Hlavka reached
11:29:39 out to Dr. Khoruts -- and we just saw this e-mail in Finch's
11:29:43 presentation -- and he reached out. He said that he was
11:29:45 being introduced by Judy Berman, that this article had been
11:29:49 brought to his attention and he said, "The article was very
11:29:52 interesting and I was surprised to note that this represents
11:29:55 some of the first objective evidence for the mode of action
11:29:59 for fecal transplant."
11:30:00 And we heard a suggestion earlier in the
11:30:03 testimony that this was an acknowledgment that the
11:30:06 University of Minnesota folks were first.
11:30:09 And I want to be very clear about who was doing
11:30:13 what and who was the first to do what because I'm not
11:30:16 claiming that we were the first to do everything. I am
11:30:20 saying that we were the first to come up with this idea of a
11:30:24 stool bank and some of the processing steps that you would
11:30:26 want to take, if that's what you were doing.

But in terms of doing the work that Dr. Khoruts presented that he had done back in 2008 on that first patient, Nancy, that was important for the patient, that was an important advance, and I want to be very clear that we are giving full credit for that. Dr. Khoruts was also very clear, though, that when he treated that first patient, Nancy, he did so having read the ways that people had done it before and following those old methods.

You may remember he said he borrowed a blender from Dr. Sadowsky, whizzed it up, gave it to her and it was so smelly that the nurses had to run around with -- you know, try to deodorize afterwards and he had to shut down the whole surgery center. Those were the old methods. That's not the invention that the University of Minnesota is saying they made in this case. That was old school FMT. And he wrote about it and he wrote about understanding specifically what had happened with her and her treatment. That's what Dr. -- that's what Mr. Hlavka read about. He said it was some of the first objective evidence for the mode of action for fecal transplant, the details of how fecal transplant works. We're not saying we invented that. Also, I don't think that's what any of the patents in this case were about. And then he said, "I am exploring the business commercial viability of fecal transplantation and/or bacteria therapy, I'm interested in talking to you."

11:32:00 Now, Dr. Khoruts response to that outreach was, "I'm not sure we need an outside person to explore the business commercial viability of poop," and I think it's fair to say that at this point in time that's not something that was foremost in their mind.

11:32:16 Now, they did go on to have more discussions with Mr. Hlavka and Mr. Berman. In June of 2010, Mr. Hlavka and Mr. Berman sent Mike Sadowsky their business plan and they talked about it, but they didn't move forward together. And from Mr. Berman and Mr. Hlavka's perspective that sort of was that.

11:32:37 It is clear though that at some point Dr. Khoruts and Dr. Sadowsky got interested in this idea that maybe there could be a business, maybe there was something here that you could turn into a commercial product because by the time they met Lee Jones, they were already, as you heard, talking to the folks at NuQure, talking to the venture capital folks about maybe trying to do something on the business side.

11:33:03 Now, you heard that Lee Jones has a very long history with the University of Minnesota and she took the position as CEO-in-Residence and I think she explained to you she absolutely thought her job was to try to help the University and to do so by talking to the scientists there, exploring was there a business opportunity, and if so,

11:33:25 potentially working with them to start a company based on
11:33:30 that technology.
11:33:31 And I would submit to you that's exactly what
11:33:34 she did. She met with them, she introduced them to
11:33:38 consultants to help them understand the regulatory
11:33:41 landscape. And after doing her due diligence, she said I
11:33:45 really want to do this and she made a proposal for them to
11:33:51 work together. Now, this wasn't a take it or leave it
11:33:54 offer. She asked them to contribute and to suggest how they
11:33:59 would like this relationship to work, but she made a
11:34:02 reasonably detailed proposal and I would suggest to you this
11:34:05 was a pretty fair proposal.
11:34:10 Now, one of the terms was a license of existing
11:34:14 technology from the University of Minnesota and the transfer
11:34:17 of technology from MicrobEX lab to newco for manufacture,
11:34:21 and there was some suggestion that during the trial that --
11:34:25 because she said here, one of the terms would be a license,
11:34:28 that she understood back in 2011 that she would need a
11:34:32 license.
11:34:33 Now, I want to be clear. She was proposing a
11:34:35 transfer of technology from Dr. Sadowsky's lab to the new
11:34:41 company for manufacturing. So, if you're going to use the
11:34:44 University of Minnesota's technology and transfer it, of
11:34:47 course you need a license. That doesn't mean you need a
11:34:50 license if you're going to go do something different. And

11:34:54 of course, that license would have been for the University
11:34:59 of Minnesota process, which at the time, as you heard
11:35:02 described, was this process that used a blender, used the
11:35:06 sequential sieve, spun it, and then suspended it. That's
11:35:09 what she would have been taking a license to and had she
11:35:11 followed -- had they followed through with this proposal,
11:35:16 that technology, presumably, would have been the starting
11:35:18 point.

11:35:19 Now, she also proposed a consulting relationship
11:35:22 with both Dr. Sadowsky and Dr. Khoruts and you heard
11:35:26 Dr. Khoruts say, essentially, this was a nonstarter from his
11:35:29 point of view, that his whole career doesn't point in this
11:35:32 commercial drug direction, that's not who I was. But you
11:35:36 also heard that in connection with their relationship with
11:35:41 NuQure, the folks that they were talking to, both
11:35:44 Dr. Khoruts and Dr. Sadowsky asked to enter into consulting
11:35:49 agreements. So the fact that consulting agreements were
11:35:54 proposed as part of the deal, I think it's pretty clearly
11:35:58 not the reason it didn't happen. The reason it didn't
11:36:00 happen, and I think Dr. Khoruts admitted this, is that they
11:36:05 turned down Lee Jones because they had already made a
11:36:09 commitment to and were already working with NuQure. Now,
11:36:14 that's fine.

11:36:16 As Lee Jones said, they didn't have an
11:36:19 obligation to work with her. She didn't have an obligation

11:36:22 to work with them. But having made a fair proposal and
11:36:27 being turned down, she then decided this is too important.
11:36:31 And you heard her say that, this is too important for me not
11:36:34 to try to take this public FMT technology and bring it to
11:36:40 patients. And that's what she did, working with Mike Berman
11:36:44 and Ed Hlavka and relying on the intellectual property that
11:36:50 had been developed back -- and filed for back in February of
11:36:54 2010, well before the patents that are at issue in this
11:36:59 case. And they moved forward, using as a foundation, that
11:37:05 intellectual property from Hlavka, which resulted in this
11:37:08 issued patent, as well as making additional innovations that
11:37:14 resulted in additional patents, including this patent that
11:37:16 was issued to Lee Jones and Courtney Jones and a couple of
11:37:20 the other folks who worked at Rebiotix.

11:37:24 Now, you heard that the University of Minnesota
11:37:31 has, as recently as 2021, recognized and celebrated Lee
11:37:41 Jones's accomplishments as the president and CEO of
11:37:46 Rebiotix. And what you've heard now is, well, we didn't
11:37:49 know in 2021 that she had done anything wrong, we only
11:37:54 learned about that on the first day of trial.

11:37:58 But I want you to consider that you have heard,
11:38:02 I think over and over, and, in fact, just now, the
11:38:06 suggestion that she did do something wrong by working with
11:38:11 the inventors from the University of Minnesota in 2011 and
11:38:16 then going out and starting her own company. And you have

heard over and over from witnesses on the plaintiffs' side in this case that in their view, there is no way to have a successful commercial product without using their inventions.

Now, if those things are true, those are certainly things they knew in 2021. And yet as you're going to see over and over, they acknowledged the ways in which she had made contributions and they never called into question the work that she had done starting Rebiotix. And I think that may be why in the opening statement in this case, things took a pretty sharp turn.

You will remember, I think this opening demonstrative that was shown to you with Ferring climbing -- the sort of dark figure climbing over the fence to break into the, you know, place that's got the two nice, white houses in it. And I don't think there's any way to read that other than as a suggestion that Ms. Jones did something wrong by pursuing this opportunity.

I did characterize that image as a burglary and I will say, that's what it looks like to me. Obviously, you can draw your own conclusions. But I think the reason that we are talking so much in this case about things that are not about patent infringement is because they want you to believe this. And they are relying on this to try to influence your perception of the patent case. So I want to

talk about this.

Because the first thing is that they made a deal about the fact that Ms. Jones had documents on her computer from when she was doing this work with the University of Minnesota people. She did. She explained she was surprised by that, but she did. But I want you to bear in mind, there was nothing wrong with that. The NDA that she signed allowed her to keep a copy of the documents, they sent them to her Gmail. She was using her home computer. She never purged them, she never had any obligation to. So they tried to suggest that there was something really sinister and wrong about these documents. And you may remember this slide from opening, this was sort of presented, I think, as being the smoking gun, very red, very -- and Rebiotix found or disseminated UMN's evaluation of patented invention to Rebiotix team. And this was an UMN analysis of invention document. And they made that sound pretty bad.

I think what you heard over the course of the trial is what this actually was, was a presentation put together by a group of students -- that Lee Jones helps them put that together, student mentoring is part of what she does at the University and that this was publicly presented, which I think is pretty different from the way that it was initially presented to you.

One of the other documents that we've heard a

lot about is this Hamilton 2012 paper. And it's true, folks were looking at and studying that paper and they did think that it was helpful to learn more about FMT. And I would suggest to you, that's how science works. This is a pretty small community, everyone reads everyone's papers. That's actually why you publish papers, the reason you publish papers is so that other people will read them. This was public. There is nothing wrong at looking at somebody else's published paper in order to understand what they were doing.

Now, there were four documents that were presented to you that Lee Jones had in her file; two of them were public and two of them were documents about the patent application. There was the patent application itself and then there was this sort of stage-gate document that describes what they were going to file for a patent. And at the end of the day, the only thing they've pointed you to in those documents, that they're saying, this was the confidential secret sauce thing that she was aware of, was the University of Minnesota protocol. And that University of Minnesota protocol was this.

Now, the only thing in that protocol that she actually wound up using the same thing as, was starting with 50 grams of donor feces. They did that, and she did that. And you heard Dr. Khoruts say, he came up with that in part

11:43:07 from reading the literature and in part because that's how much a person can produce. That's not their secret sauce information. Every single other thing that's in that protocol is something that we do differently. Everything. The buffered saline, the Waring blender, the nitrogen, the series of four sieves, the centrifuging, the glycerol, the suspension, it's all different.

Now, we showed you in the opening, this demonstrative to illustrate that that process that they're saying we had access to is completely different from the process that we developed.

Now, I just heard a criticism that we were making a comparison and suggesting that somehow we shouldn't be comparing our process to the University of Minnesota processes. I want to say, I agree. That's not the patent infringement question, but that is the question about the information that she had access to and whether she copied it and the answer to that question is very clearly no, because what she wound up doing and what the people at Rebiotix wound up doing was completely different from the process that the University of Minnesota inventors had developed.

She used, by way of example, a Stomacher and you heard Courtney Jones explain, they did testing and why it is they wound up deciding that a Stomacher was the right piece of instrumention to use as a part of this process rather

than a blender and sieves. And there was some suggestion, I think in the testimony that may be there was a reference to the Stomacher in the patent. I just want to be clear, there's not.

You'll have the patent, you can look through it yourself, it does not say anything about the possibility of using a Stomacher as part of the process.

Now, you also heard just now -- and I think it was actually one of the first exhibits they showed you, a reference to this e-mail from Mark Anderson, that he says, "The current manufacturing process is CGMP compliant and was derived from the Hamilton procedure described in Appendix 4 of the RFP and additional landmark papers including Brandt, Borody, Van Nood and Khoruts," so that is a citation to a number of papers, many of which were in the prior art, dating back even before the work that Dr. Khoruts had done that set forth the basis of FMT. And it is true that we do not say that we invented FMT but then -- it then goes on to say, "these were combined with the process development completed by Rebiotix" and it talks about the resulting manufacturing process.

It cites the Hamilton paper as one of the references, but I would suggest that when you actually look at the record of what is the process that we developed, you know that it is very different from that process in the

11:46:08 Hamilton paper. As I said, the only thing it has in common
11:46:13 is the starting point of 50 grams of donor feces. And there
11:46:18 was no hiding the ball here. I want to be clear that when
11:46:22 Lee Jones filed her patent application, she cited all of
11:46:27 Dr. Khoruts' work, all of Matt Hamilton's work, all of that
11:46:32 was cited to the patent office. There was no hiding the
11:46:35 ball about any of that. And that brings me to the question
11:46:40 of infringement.

11:46:42 So you heard that infringement requires you to
11:46:47 compare what's in the claims with the product. And in doing
11:46:52 that, you have to compare the product or method with every
11:46:56 requirement that's in the claims. And this is a really
11:47:00 important point, because close enough isn't good enough. In
11:47:06 order to have literal infringement, every single thing has
11:47:12 to be met.

11:47:12 So in the patent, let's imagine that you have a
11:47:15 patent on a chocolate chip cookies, so chocolate chip cookie
11:47:20 and let's say that your claim says, I have invented a
11:47:23 chocolate chip cookie that has flour, sugar, butter and
11:47:27 chocolate chips in it and someone else comes along and they
11:47:31 made the cookie and the cookie has flour, sugar, butter and
11:47:33 nuts. How do you decide if it's infringing? You go through
11:47:38 and you compare the nut cookie with the claim, it has flour,
11:47:43 it has sugar, it has butter but it has nuts instead of
11:47:47 chocolate chips. That means you don't infringe. And that

11:47:50 means you don't infringe even though they both have flour,
11:47:54 they both have sugar, they both have butter.
11:47:59 So in order to find infringement, you have to
11:48:01 find that every single thing is there.
11:48:04 The other important point about infringement is
11:48:09 that it is Finch's burden of proof. So Finch is the one
11:48:13 that has to come in and prove to you, prove to your
11:48:18 satisfaction that we infringe. So what is the fight about?
11:48:24 What do we disagree about?
11:48:28 The issue is whether REBYOTA -- and you're going
11:48:32 to have this in the jury room because you get the evidence,
11:48:36 and you can ask to look at and inspect and see the evidence.
11:48:40 And I encourage you to do that, but you're going to have --
11:48:43 you're going to have two packages of REBYOTA. The question
11:48:47 is whether this thing is capable of passing through a .5
11:48:53 millimeter sieve. And if it doesn't, we don't infringe.
11:48:59 So, remember, it's Finch's burden of proof. Did Finch prove
11:49:03 that that thing, REBYOTA, is capable of passing through a .5
11:49:09 p.m. sieve?
11:49:09 So what does it mean to meet the burden of
11:49:13 proof? First, you have to have proof, then you put it on
11:49:15 the table and you show why that proof is enough to prove the
11:49:19 point that you're trying to make. So what did they come in
11:49:24 with? Dr. Benson came in and gave his opinion about whether
11:49:29 REBYOTA is capable of passing through a .5 millimeter sieve

and what he said is, REBYOTA is manufactured in such a way that it is filtered through a .5 millimeter filter and indeed, it is capable of passing through .5 millimeters. That was the evidence that they presented to you, so basically what he was saying was, well, this is a bag, this is the bag that goes in the Stomacher, it is specified as having .5 millimeter pores, that means whatever comes out of here, must be capable of passing through this. And I would suggest to you, that's just not right.

You'll have both of these things too. You can test it for yourself, but you can try putting this paperclip through one of these pores, you can do it. You can try putting this paperclip through the .5 millimeter sieve, it doesn't go through. The fact that something came out of here does not mean that it can go through here. Because this is rigid and this is flexible. And the thing about this that's important, by the way, it's not that the pore size is approximately 5(sic) millimeters but that it's flexible and those pores can stretch. And you can check that out for yourself too and see what that looks like.

Now, Dr. Benson said it must be right. He didn't do any actual testing to see whether his assumption that if something came out of this Stomacher bag, it must be able to go through this, was correct. And you heard him say over and over, "Well, I didn't need to. I didn't need to, I

11:51:13 just assumed basically that this had to be right."

11:51:16 So I want to talk about that prune demonstration
11:51:20 and what the point of that was. The point was absolutely
11:51:23 not to suggest that REBYOTA is prunes, but it was to show
11:51:28 you how this works, because what you saw is that when that
11:51:32 prune baby food was mushed up in the Stomacher and it came
11:51:36 out through these pores, and you then put it on top of the
11:51:42 sieves, it didn't all go through.

11:51:45 And what that tells you is that going through
11:51:47 these pores and going through this sieve are different.
11:51:52 Coming out of here doesn't mean it's going through here.
11:51:57 That was the assumption that Dr. Benson made, that
11:52:00 assumption was just as a factual matter wrong. That means
11:52:07 that Finch presented to you no proof, because they never
11:52:11 actually did the experiment themselves to see whether or not
11:52:17 REBYOTA, the material that comes out, is capable of passing
11:52:22 through this sieve.

11:52:23 Now, you could be done at that point with
11:52:26 respect to the infringement question. But we did come
11:52:31 present evidence to you because we wanted you to have that
11:52:35 evidence of what happens when you actually do the testing.
11:52:38 And what you saw -- when Dr. Johnson did the testing and
11:52:42 took half of this volume of REBYOTA and powered it through
11:52:46 this .5 millimeter sieve, is that there were a bunch of
11:52:51 stuff that clogged up the pores and stuck on top of the

11:52:57 filter, on top of the sieve. It does not -- REBYOTA is not
11:53:00 capable of passing through a .5 millimeter sieve, because it
11:53:04 didn't when he did the tests.
11:53:07 And he explained why, "because it's got these
11:53:10 big chunks in it that are bigger than the size of the
11:53:14 sieve." Now, there was a sort of suggestion here that,
11:53:17 because this is blown up 40 times, these are not macroscopic
11:53:22 particles. Macroscopic just means you can see them, you
11:53:25 don't need a microscope to see them and Dr. Johnson told you
11:53:29 he could see the particles with his naked eye, he needed a
11:53:32 microscope to be able to take pictures that would allow him
11:53:35 to measure them. That's a different question. But I would
11:53:38 also say, again, you're going to have REBYOTA in the room
11:53:42 with you, you can look at it yourself if you've got any
11:53:45 questions about what this looks like. And you can make your
11:53:49 own judgment, but it has particles bigger than .5
11:53:52 millimeters in it.
11:53:53 And again, what does Finch have in response to
11:53:59 this? Nothing. They didn't do their own tests to see how
11:54:03 many particles there are, they didn't do their own tests to
11:54:06 see whether it would go through the sieves. In fact,
11:54:10 Dr. Benson testified that he didn't dispute Dr. Johnson's
11:54:14 testimony. He didn't think if he did testing, it would come
11:54:17 out any differently. And instead what they did is come in
11:54:21 with this demonstrative of the grates and the pieces of

11:54:26 cardboard and said well, if I took each individual particle
11:54:30 and I reoriented it, maybe I would be able to sort of push
11:54:34 each individual particle through.
11:54:36 Now, there's a couple of problems with this.
11:54:38 The first problem is, they didn't actually do that testing.
11:54:42 Where is the evidence that those particles, if you
11:54:44 reoriented them, would actually be able to go through this?
11:54:48 There isn't any.
11:54:49 He didn't pull out the particles. He didn't do
11:54:51 some testing to see whether individual particles would all
11:54:55 be able to go through them, and there's no way to tell from
11:54:59 a 2D image, a photo of a particle, what the dimension is of
11:55:04 that particle are in all directions and whether it would, as
11:55:07 an individual particle, be able to pass through here.
11:55:10 But there is a second problem with this, which
11:55:13 is it's not the right question. The question is not whether
11:55:15 every individual particle individually is capable of passing
11:55:19 through a .5 millimeter sieve. You're not supposed to go in
11:55:23 here and somehow pluck out every particle and put it on a
11:55:28 sieve and see whether each individual particles goes
11:55:33 through.
11:55:33 The question, what the claim says is, is the
11:55:37 fecal extract or preparation capable of passing through a .5
11:55:41 millimeter sieve. That's it. You take this thing. You
11:55:44 pour it over the sieve. And Dr. Johnson said sieving is a

11:55:49 one-pass operation. It is. You pour it over the sieve and
11:55:51 you look to see whether it is capable of passing through.
11:55:54 Now, there was a comment made in Finch's opening
11:55:58 that Dr. Johnson's test was somehow improper because he
11:56:02 didn't use a Stomacher. I don't understand that comment.
11:56:09 He took this product. This product is made using a
11:56:14 Stomacher. And then he took this product. This is the
11:56:18 fecal extract or preparation that's at issue in the claim,
11:56:21 and he tested whether this product is capable of passing
11:56:25 through a .5 millimeter sieve. That's the requirement in
11:56:30 the claim, and that's the thing that he showed is not met.
11:56:36 So because REBYOTA is not capable of passing
11:56:39 through a .5 millimeter sieve, the answer to this question
11:56:45 of whether the University and Finch have proven by a
11:56:49 preponderance of the evidence, whether they have proven that
11:56:51 we literally infringe is no.
11:56:54 Now I want to turn to this other doctrine that
11:56:57 we're talking about, just for this claim, that is called the
11:57:01 doctrine of equivalents. And you heard the jury
11:57:04 instruction, but basically, you can find infringement under
11:57:07 the doctrine of equivalents. If the differences between
11:57:10 what's claimed and the product are insubstantial or if they
11:57:15 perform substantially the same function and work in
11:57:19 substantially the same way to achieve substantially the same
11:57:23 result.

11:57:23 So you can think about this and again at a high level. Let's say you had our patent on a cookie. And somebody else had a nut cookie. Well, is a nut cookie insubstantially different from a chocolate chip cookie? I would say no especially not if you have a nut allergy but just in general, no.

But let's say somebody had a chocolate chunk cookie. Maybe you would say, "Okay, I don't think there's really a significant difference. That's basically the same thing." In that case, there would be infringement under the doctrine of equivalents.

So what is the evidence with respect to whether REBYOTA would be substantially the same? If it didn't have those larger particles in there and if it could, in fact, all flow through, all pass through this .5 millimeter sieve, does that make a difference to the product? What is the evidence on that question?

From Finch's side of the table, there's none. They didn't offer any evidence of that. What would happen? Would it make a difference to how it works? Did they test it? Did they run it through and take the product after all that material had been filtered out and see whether it works the same way? No. There's no proof of that.

Their expert got up there and said, "There's, like, you know, lots and lots of millions of particles in

it," but he didn't do any work to see whether that makes a difference and whether the big particles matter relevant to the little ones.

There is one person in this case from their side of the table who talked about that. That person was Dr. Khoruts. And he admitted that they matter. What he said, talking about this, is you can have the globs of stuff, and he said the globs are not irrelevant. They actually can matter. And I think that's exactly right.

Now, why do they matter? Well, one reason they may matter, because bacteria stick to them. So it's important to have them in there for the bacteria. We don't know all the reasons they might matter because Finch presented no evidence on that and they have the burden.

But we do know one very important thing that is different between what they say they invented and REBYOTA because what they say they invented is something that is nearly odorless. They say in the patent -- and this is at column 13, you can go look at it and read this -- "The use of sieves to extract biological material from fecal material unexpectedly resulted in a composition, which was nearly odorless." And they said this was not expected because feces normally have a distinctive odor. We all know that's true. And this was surprising to be removed by the minimal manipulation used. This is a significant advantage over the

12:00:17 Takeda method that is unaesthetic and so distasteful that
12:00:20 some patients and staff refuse to take part and changes it
12:00:23 into a method that's easily practiced in a clinical setting
or at home.

12:00:30 So they said, "That's the benefit of our
12:00:31 patented process," and that actually makes sense because in
12:00:35 that document that we were looking at where they were
12:00:38 talking about their invention, they said that their
12:00:41 researchers had created a protocol by which the donor
12:00:44 material is cleaned, purified and modified for long-term
12:00:47 storage. Their ultimate goal is to create a freeze-dried
12:00:51 product that can be delivered by an enteric release capsule.
12:00:54 And obviously, if you're putting something in a capsule,
12:00:58 it's probably really, really important that it doesn't smell
12:01:00 like poop because that would be pretty gross.

12:01:03 So what about REBYOTA? Well, you heard it from
12:01:06 Dr. Johnson. When he was working with it, smells like poop.
12:01:10 And they don't disagree. I mean, we asked Dr. Benson,
12:01:13 "You'd expect that REBYOTA actually does have an odor?" And
12:01:18 he said, "Yeah." And when you look at it, test for
12:01:24 yourself, but when you look at it, it's not surprising
12:01:27 because it's basically mushed up poop. It smells like poop.
12:01:33 That's a different result than the result that they were
12:01:38 saying was the benefit of using their invention.

12:01:42 And for that reason when you're asked whether

12:01:45 Finch and the University of Minnesota have proven by a
12:01:49 preponderance of the evidence that we infringe Claim 7 under
12:01:52 the doctrine of equivalents, they're not equivalent. And
12:01:55 for that reason we submit the correct answer to that
12:01:58 question is no.
12:02:00 Now, there's one more infringement issue. And
12:02:04 that has to do with the '309 patent, which was a requirement
12:02:08 that in some ways is similar, that the fecal bacteria is
12:02:13 separated from rough particulate matter. And as you heard,
12:02:16 the Court has said that means rough macroscopic, which means
12:02:21 you can see it with the naked eye, nonliving matter.
12:02:24 So what's the evidence? Well, again, to start
12:02:27 with, you'll have the product. You can look at it, and I
12:02:30 think you'll see when you look at it there's stuff in there
12:02:33 you can see. There's, like, little bits of chunky stuff,
12:02:37 but, again, Dr. Johnson tested it. He looked at it. He saw
12:02:42 that there are these particles that are big. He said he
12:02:45 could see them with the naked eye, and when he looked at
12:02:48 them under the microscope, they are not living matter. It's
12:02:51 plant matter, undigested plant matter, basically.
12:02:55 And this is in REBYOTA, in here where we also
12:03:00 have all of the bacteria. So in REBYOTA -- and that's the
12:03:04 question, right? The claim is, in REBYOTA, are the bacteria
12:03:08 separated from rough particulate matter, in here. And the
12:03:12 answer is no because in here, there's bacteria, and in here,

there's rough particulate matter. And so in here, they are not separated from each other. They are all together in there happily with the bacteria eating up that little rough particulate matter as time goes on.

Dr. Johnson explained that in his testimony, that he clearly saw rough particulate matter. And I think this is basically undisputed. This is undisputed. I don't think there's really a serious argument that if you look in here, you're not going to be able to see particles that are visible to the naked eye. And I certainly don't think it's disputed that there's bacteria in here. That's the infringement question.

Now, what Dr. Benson did is come in and say, well, there's some separation that's occurring. So what is he talking about? So I want you to imagine that the blue ones are rough, macroscopic particulate matter and that the orange ones are bacteria. So you start off by putting the fecal sample and some water inside the inner bag, right? And so inside the inner bag, I've got both red and blue M&M's, and then we go through the Stomacher process. It all gets mushed and squeezed through the inner pores. And what do we wind up with?

We wind up with a few blue things, some rough macroscopic material that's still inside the bag. That was the point of the one experiment that Dr. Benson did do to

12:04:50 show that there's some stuff still inside the bag. That's
12:04:53 true. We don't disagree with that.
12:04:54 The thing that's important though is that
12:04:57 outside the bag, which is the thing that becomes REBYOTA,
12:05:00 there's both orange and blue. There's both rough
12:05:04 macroscopic material and bacteria. So have the orange M&M's
12:05:08 been separated from the blue M&M's?
12:05:12 The answer to that question is no because they
12:05:14 are all here together. They're not separated from each
12:05:17 other, and they are certainly not separated from each other
12:05:21 when they get put into this package and when this thing gets
12:05:26 sold as REBYOTA because both the rough macroscopic material
12:05:32 and the bacteria are all mixed together in there.
12:05:35 So with respect to infringement of the two
12:05:39 claims of the '309 patent, both of which have that
12:05:42 requirement, the answer to that question is no.
12:05:45 Now, I'm not going to talk about infringement of
12:05:49 the '080 patent. We think the '080 patent is invalid, and
12:05:55 I'm going to talk to you about why we think that is and why
12:05:58 we think there's not any difference between what Dr. Borody
12:06:03 said he invented in March of 2011 and what Mr. Hlavka
12:06:07 already had invented in February of 2010. And if we're
12:06:12 right about that, whether we infringe or not doesn't matter,
12:06:16 because you can't trample on rights that somebody doesn't
12:06:21 have. If the patent is invalid, it's invalid. But I'm not

12:06:25 going to argue with you about infringement for '080. I'm
12:06:29 only going to talk to you about invalidity.
12:06:32 So let me talk to you about invalidity. So what
12:06:35 does this mean? It's a defense in an infringement lawsuit
12:06:38 that the patent is invalid. I think it's a very normal
12:06:41 reaction to think to yourself, well, the Patent Office
12:06:44 issued it. What does that even mean to be invalid? But
12:06:48 what you heard in the patent video is that this is a very
12:06:51 important part of this jury trial process. This is why
12:06:55 we're here. You guys are the ones that get to decide the
12:07:00 invalidity question.
12:07:02 And that's because we recognize that sometimes
12:07:05 the government gets it wrong. We recognize that patent
12:07:10 examiners can make mistakes. That's actually in the patent
12:07:14 video. Mistakes can happen. No process is perfect. It's
12:07:18 also because this is the first time that we get to tell our
12:07:21 side of the story.
12:07:22 So if you think about how the examination
12:07:25 process works, the applicant, Finch, files their patent
12:07:28 application, the examiner looks at it, and they go back and
12:07:32 forth and they talk to each other about whether the claims
12:07:35 should issue. And Finch gets to plead its case and we're
12:07:38 going to see here how they did plead their case to the
12:07:41 Patent Office. But we're not there. We don't get to say
12:07:45 actually we don't think that's right.

12:07:47 So the patent examiner is in a little bit like
12:07:49 the position you were in at the very beginning of the trial
12:07:51 when you had heard their opening statement and you hadn't
12:07:54 heard ours. And if you think back to what your state of
12:07:57 mind was at that point in time, it probably sounded like
12:08:00 they had a really good case because you hadn't heard our
12:08:03 side of the story.
12:08:04 That's the position the examiner is in, and
12:08:07 that's why the system recognizes you should get to hear both
12:08:10 sides of the story, and then you are the ones ultimately who
12:08:14 make that decision about whether the patent is valid or not.
12:08:18 We have the burden of proof, and we have the
12:08:21 burden of proof on that question by clear and convincing
12:08:25 evidence. So we need to present evidence to you that you
12:08:27 think is clear and that you think is convincing, and it is
12:08:31 then your job to decide whether we have done it and whether
12:08:34 you accept that evidence.
12:08:35 And we presented to you testimony from two
12:08:38 experts on this matter. Dr. Treangen talked about the
12:08:41 University of Minnesota patent, and Dr. Britton talked about
12:08:45 the Borody patents. And they explained to you and walked
12:08:50 you through why we think there was a mistake made with
12:08:54 respect to issuing both of those sets of patents.
12:08:58 Now, we have experts. Finch has experts. And
12:09:05 you heard -- you heard from Dr. Benson. He was their

validity expert on the Borody patents as well as their expert on infringement. And there was Dr. Schloss, who you heard reference to. They were both here Monday, they were here Tuesday, they were here Wednesday. They heard the testimony from our experts, and they left. Neither of them took the stand to testify and say that anything that our experts had said was wrong.

So I want you to really think about that because that's pretty important. Neither of them took the stand and said when Dr. Treangen just said that, that was wrong. When Dr. Britton said that, I disagree. There was no contrary expert testimony on validity at all.

So I want to start with the University of Minnesota patent. And the question for you is whether the inventors had possession of the invention when they filed for the patent. You're going to get a jury instruction on this. In fact, you heard one read to you, and that's what it says. We have to show -- the question is whether the inventor possessed the subject matter finally claimed in the patent on or before the effective filing date.

So why are we worried about this? What's up with this possession? So sort of an interesting thing about patents, but the way the system works, you file your patent application and you include all of this text, right? So there's a lot of references considered, and then there's the

figure and there's description and you talk in words about what you think your invention is. And you submit all of that when you file the patent. Then, you have this back and forth process with the examiner, which can go on for years and years and years and years because you'll see in the case of these patents, they were filed for here in 2011. This patent, which is the '080 patent, it issued on January 3rd of 2023. So there was a lot of time that went by.

And over the course of that time, Finch gets to keep presenting new claims and say, all right, maybe you don't like this claim, how about this one? You don't like that one, how about this one?

So you can be proposing a claim years after you filed for the patent and years after you say that you made the invention, and that timing is really important because in patents, who's first really is the critical question. So the reason this requirement exists is to make sure that you don't come along later and claim something that is broader than what you actually taught in the patent application when you filed back when you say you made your invention.

So how does that apply here? So this claim requires a couple of things that are important to this discussion. It requires that you have this fecal extract that passes through a .5 millimeter sieve and it requires that this method results in having the relative abundance of

12:12:42 members of the phylum's Proteobacteria be reduced by at
12:12:47 least 10% following the administration of that composition
12:12:50 made using that method.
12:12:52 Now, I want to be really clear here, this claim
12:12:55 is not about whether FMT works. FMT had been known to work
12:12:59 for a very long time. This claim is about that specific
12:13:05 requirement of reducing Proteobacteria by at least 10%,
12:13:09 right, that's the new thing here. Does that actually
12:13:13 happen?
12:13:13 This is important because you heard reference to
12:13:16 the fact that in the patent they talk about 43 patients who
12:13:19 were treated with FMT and they say the patients were treated
12:13:22 with FMT and they got better. Absolutely, they did. But
12:13:27 that's -- that's what we knew before, right.
12:13:31 Dr. Khoruts and Dr. Sadowsky didn't invent the
12:13:33 idea that using FMT would make people better, that had been
12:13:37 known for a very long time, right. We saw published reports
12:13:42 of that from the '50s through the '80s. What they were
12:13:46 saying they invented here was we've got the process that
12:13:48 uses a .5 millimeter sieve and you can use that process and
12:13:52 make this particular change in the percentage of
12:13:56 Proteobacteria that you've got relative to other things.
12:14:00 That's our invention.
12:14:01 And the question is did they really have support
12:14:04 for that back when they filed their patent application?

Now, this thing, reducing the Proteobacteria by 10%, Dr. Khoruts agreed that's referred to as taxonomic data. That Proteobacteria is the taxonomy of the bacteria. So we call that taxonomic data. This figure, what you're going to see in the patent, there's figure 1 and figure 2 are the taxonomic data in the patent that talks about or tries to talk about or show percentages of different things, Firmicutes, Proteobacteria, fusobacteria, et cetera, et cetera.

There are a bunch of problems with this chart. The first problem is you can't read it. Dr. Hamilton tried to read it. He had a color copy; he couldn't read it. He said it was extremely difficult in black and white and then I think he got a color copy. He still couldn't read it.

Dr. Treangen can't read it. It doesn't have a supporting table. What's that about? What Dr. Treangen explained is that normally in the literature when you have that kind of a figure, you've got a table that gives all of the underlying data and says what all the percentage changes were. So you can eyeball the thing but you have actually got the numbers right next to it, or online where you can access it. That's what you normally do; the inventors didn't do that. So none of that data is actually in the patent. So that's why Dr. Treangen was saying, "I can't really tell that much just from eyeballing it."

12:15:43 Now, he got asked a question about Dr. Schloss.
12:15:46 He said, "I don't whether Dr. Schloss could read it. I
12:15:49 couldn't, I don't know whether he can." That's interesting.
12:15:52 We don't know either because Dr. Schloss didn't come and
12:15:56 take the stand and tell you whether he could read it or not,
12:16:00 right? Draw your own conclusions.
12:16:04 What else is the problem with the table? The
12:16:07 underlying data doesn't exist anymore. There's no way now
12:16:10 to go back and check because the data is not in the patent
12:16:14 and we know from Dr. Treangen that the data was destroyed.
12:16:19 There is no way to go back and check and look at that data
12:16:22 and see what it actually said.
12:16:25 There's another problem, all of the data in that
12:16:30 table comes from one patient, just one. They did treat
12:16:34 43 patients and 43 patients or some percentage, I don't
12:16:40 remember what, got better. But in terms of actually
12:16:44 understanding what was happening to their Proteobacteria,
12:16:47 it's one.
12:16:48 And this is not in dispute. Dr. Khoruts agrees
12:16:50 with this. I asked him, "We can agree the only taxonomic
12:16:53 data in your patent about specific changes to specific
12:16:56 bacteria in the gut microbiome was one patient?" Agreed.
12:17:01 Another way to say that is the sample size is N
12:17:04 of 1, right? Correct.
12:17:06 There's no dispute about that. There is data,

12:17:08 taxonomic data, in the patent for one patient and that's a
12:17:14 problem. Back in the day, back before we had this dispute,
12:17:19 Dr. Khoruts agreed, right, N of 1 is not science and there's
12:17:24 good reason for that because as you heard, there is no such
12:17:28 thing as one healthy gut microbiome. Mine is different from
12:17:32 yourself, right? How my gut is going to respond to milk or
12:17:37 gluten or whatever is not necessarily the same as yours and
12:17:40 so what happens in one patient with respect to how their
12:17:45 Proteobacteria changed and whether it did change by 10%,
12:17:49 that doesn't tell you what's going to happen to everyone
12:17:51 else. You've got to do a study. You've got to give it to a
12:17:55 bunch of people and see what happens and then analyze those
12:17:59 results. And what you heard is that they didn't do that
12:18:05 work before they filed the patent. They only have results
12:18:09 for a single patient. So that's the only thing that's in
12:18:12 there.

12:18:12 There's another problem. That one patient that
12:18:15 they had results for, didn't even get the patented method.
12:18:19 She was treated the old way. She was treated the same way
12:18:24 that Nancy was treated. You get the poop, you whiz it up in
12:18:28 a blender, you put it through, like, a tea strainer and up
12:18:32 it goes. That's what the patent says. It says figure 1
12:18:36 comes from the patient who got the thing in example 1. I
12:18:40 asked Dr. Khoruts about example 1 and he agreed this was
12:18:45 just -- he got the poop from her son, remember this was a

12:18:49 patient-identified donor, whizzed it up and gave it to her.

12:18:52 So, even if it tells you something about the
12:18:55 change in Proteobacteria for that one patient, although you
12:18:58 can't read the table to really tell what that change was, it
12:19:02 doesn't tell you anything about using the patented method
12:19:06 because they didn't use the patented method on that patient.

12:19:10 So what really happened here is that in filing
12:19:15 the patent application, the University of Minnesota jumped
12:19:18 the gun. I'm not casting any aspersions on Dr. Khoruts'
12:19:22 work, he did good and important work, but in terms of when
12:19:25 they filed the patent application, I would submit to you
12:19:28 they were rushing to get it on file. They had data from one
12:19:31 patient, not with the patented method, they put that in and
12:19:35 they were like, let's get it on file and they jumped the
12:19:38 gun.

12:19:38 And when you look at the patent, I think you're
12:19:41 going to see this. They hadn't even really identified 10%
12:19:45 as being a special number. It just says 10%, 20%, 30%, 40%.
12:19:51 And they actually say in the patent that they don't yet have
all of the results.

12:19:59 What do they say? "The complexity of donor
material preparation -- this is column 28, you can read
12:20:05 it -- technical inability to culture most of the contained
microbial constituents by classic lab techniques," that
12:20:11 means it's really hard to grow the bacteria, which you need

12:20:14 to be able to do in order to figure out what they are and
12:20:16 what percentage of them you have; we're having a problem
12:20:20 doing that -- "and our ignorance as to the identity of
12:20:24 species that are therapeutically most important" -- we're
12:20:28 not even sure which of these bacteria we care about --
12:20:31 "precluded simple tests of donor material prior to FMT that
12:20:35 could predict its efficacy. However, we are currently
12:20:39 working to characterize the microbial composition of donor
12:20:43 material and recipient fecal samples collected over time.
12:20:47 Results of these experiments should provide some means to
12:20:50 compare different donor preparations and we are working to
12:20:53 develop practical laboratory tests."
12:20:57 So, look, you don't get a patent simply because
12:21:01 you're working on something. You get a patent because you
12:21:04 proved that it works. They were working on characterizing
12:21:10 the microbial composition that would ultimately tell them
12:21:16 whether their method when they tested it in patients
12:21:19 resulted in this 10% change. But they hadn't done that work
12:21:25 yet and that means this isn't something they can claim to
12:21:29 have invented back when they filed the patent application
12:21:33 because the data is not in their to support what they
12:21:37 ultimately claimed. And that is why this requirement that
12:21:42 first -- and that's why this requirement that you have that
12:21:46 10% change in Proteobacteria using this method is not set
12:21:52 forth in the patent. They don't have the data.

12:21:57 Now, there's another problem. It says it's got
12:22:00 to be capable of passing through .5 millimeter sieve. So
12:22:04 why .5, right? Why that very specific requirement? Take a
12:22:08 look at the patent. They didn't say you should use .5.
12:22:15 They said use a filter and basically listed -- or use a
12:22:21 sieve and basically listed every single size of sieve
12:22:26 imaginable. And then, when they actually did the
12:22:28 experimental work in the patent, did they stop at .5? No.
12:22:34 Every single time they talk about the specific work that
12:22:36 they did and what their protocol is, it stops as .25. It
12:22:40 doesn't stop at .5.
12:22:42 Now, you heard some testimony that said, oh, you
12:22:45 know, at some point, we did some work and we decided to
12:22:48 start stopping at .5. That's not in the patent and we have
12:22:53 no way of knowing when that happened.
12:22:57 Now, Dr. Sadowsky agrees, nowhere in the patent
12:23:01 does it describe stopping at .5, right? It doesn't. He did
12:23:07 document and Dr. Khoruts did document the experimental work
12:23:11 that they did. Those experiments were documented in
12:23:14 notebooks that were maintained by Dr. Sadowsky.
12:23:18 Now, I want to be clear. Scientists keep
12:23:21 notebooks, lab notebooks. This is like one of the basic
12:23:24 things that scientists do. You do experiments, you write it
12:23:27 down in your lab notebook. As you heard, often the lab
12:23:31 notebook pages will be signed, witnessed, and dated so you

know when particular things happened. If there's ever a dispute about who did something first, you've got -- you've got the evidence and that is good laboratory practice. You heard that from Dr. Johnson. Dr. Sadowsky didn't disagree, right? He understands that lab notebooks are very important and that he would document in those lab notebooks work that he did with various sizes of sieves. So it would be interesting to go back, right, and know at this time what were the experiments that you were doing. Did you ever do an experiment just with a .5 sieve? What happened? Did you think that worked? Did you think it didn't work? Did you think there was a reason that you always needed to go down to .25? We're not going to know.

Dr. Sadowsky had all of his lab notebooks before he retired. You keep them as a scientist, so he had kept all of them. Remember he said he had 100. He had the lab notebooks documenting his entire career. And then what happened? I asked him, "What you did is threw them away?" He said, "I put them into the recycling bin."

Now, he agreed he could have gotten a dolly and gotten some boxes and taken those lab notebooks over to Dr. Khoruts, also worked at the University. They were going to continue working on the project together. This included Dr. Hamilton's lab notebooks, too. All of them. All of them got recycled. So we don't have any way of knowing what

12:25:03 the actual work back in the day was and, critically, we
12:25:08 don't have any way of knowing when it was that they decided
12:25:12 that .5 was a special number.
12:25:17 So has Ferring proven by clear and convincing
12:25:20 evidence that Claim 7 of the University of Minnesota patent
12:25:23 is invalid for lack of written description? I think we
12:25:27 have.
12:25:27 We've presented expert testimony to you,
12:25:30 Dr. Treangen explained to you why he believed that to be
12:25:35 true. Their expert sat there and listened to it and had
12:25:41 nothing to say in response, and we think that is clear and
12:25:47 convincing evidence that you can rely on in finding that
12:25:50 claim to be invalid.
12:25:51 That brings us to the two Borody patents, both
12:25:56 of which date back to March 7th of 2011, which is a little
12:26:00 over a year after Mr. Hlavka filed his patent application.
12:26:05 And here, the issue I want to talk to you about is
12:26:08 obviousness because under the patent laws, you can't get a
12:26:13 valid patent on something that is obvious. And if you think
12:26:17 about it, that makes sense because when you get a patent on
12:26:20 something, you're taking it out of the public domain, right?
12:26:24 Nobody else can use the thing that you patented.
12:26:27 And if something is obvious, it's not your invention.
12:26:32 Everyone should be free to use something that is obvious
12:26:37 because you didn't invent it, and that's why this is a

12:26:42 requirement of a valid patent. It has to be not obvious in
12:26:45 light of what came before it.
12:26:47 So how do you figure that out? There are some
12:26:50 things you look at. I want to be clear this is not all of
12:26:53 them, this is only -- there is four of them, this is just
12:26:55 three. But the one I want to talk about is two. It's the
12:26:58 differences between the claimed invention and the prior art,
12:27:01 that is one of those things that you're supposed to look at.
12:27:05 What came before, what's in the prior art, what are they
12:27:08 claiming to have invented, what's the difference? And then
12:27:11 you look at that difference and you decide, was that
12:27:14 difference obvious.
12:27:17 So here's the basic timeline, right. We know
12:27:20 that Hlavka filed his patent applications, there's actually
12:27:24 two of them, before Dr. Borody and we know that people had
12:27:28 been doing FMT for a really long time, right. So whatever
12:27:31 it is that Dr. Borody invented in 2011, it's not FMT, right.
12:27:37 It has to be something over and above that and critically,
12:27:40 it has to be something over and above what Mr. Hlavka filed
12:27:46 his patent application on. So let's take a look. What did
12:27:49 Dr. Borody invent?
12:27:50 I thought that was really interesting, because
12:27:54 Mark Smith was asked this question at his deposition.
12:27:57 Remember, he was the guy who is the former CEO of Finch and
12:28:01 what he said is, the Borody discoveries that you can sort

12:28:07 of -- "use sort of a centralized donor system in order to
12:28:09 dramatically expedite that process really enabled the field
12:28:13 to move forward." So part of that is true, the idea that a
12:28:18 centralized donor system dramatically expedited a process
12:28:22 and really enabled the field to move forward, that's true,
12:28:27 we agree with that, but that's not Dr. Borody's invention,
12:28:31 because that's what the Hlavka patent is about.
12:28:33 It is about having this centralized
12:28:38 Bacteriotherapy bank in order to have a pool of anonymous
12:28:46 prescreened donors and stock frozen stool for subsequent
12:28:48 use, these procedures and processes for how you're going to
12:28:49 do it, that was his invention. So whatever it is that
12:28:52 Dr. Borody invented in 2011, can't be that, because that was
12:28:56 already out there. And it's not just that Mr. Hlavka
12:28:59 applied for that, the patent office gave him a patent that
12:29:02 included, among other things, a temperature-controlled
12:29:05 storage bank as well as all of these other requirements.
12:29:08 And that patent, like the patents at issue in
12:29:10 this case is presumed to be valid, right. Unless you show
12:29:13 otherwise, we presume, that is a valid patent. So I want to
12:29:18 explain to you why it is that we think that the '080 patent
12:29:23 doesn't add anything to Hlavka, why it's obvious over
12:29:28 Hlavka, that there's not any invention there over and above
12:29:32 what Mr. Hlavka had already done. So I want to start by
12:29:35 saying that's where the patent office started. When claims

were initially presented to the patent office for the '080, the examiner rejected them as being obvious over Hlavka. That was the starting point. So that was the examiner's initial view when looking at the claims.

But remember, I said Finch gets to go in and plead its case, right. And that's what they did. So they said, look, there's two things that are not in Hlavka. They said the office hasn't shown that it has uncultured nonpathogenic bacteria, and it hasn't shown that the compositions is stable during long-term storage when frozen and that means at least 12 months. They didn't fight about other things, right, but they said those two things are missing. So let's look at those two things.

Uncultured, nonpathogenic bacteria and the examiner agreed, that was what the examiner said, Finch went in, Finch pled its case, Finch said those things are new and the examiner said, okay, and issued that. And said, this is why I'm doing it. Hlavka doesn't teach the fecal bacteria are uncultured and that the bacteria cryoprotectant mixture is stable during long -term storage. So the fecal bacteria are uncultured, what does that mean?

Culturing the bacteria basically means growing them up. It means growing them up so you've got a lot more bacteria than you started with. So if the fecal bacteria is uncultured, that basically means you've just got poop as

12:31:05 opposed to trying to extract the bacteria and grow up the
12:31:09 bacteria so you've got a higher percentage of it. So
12:31:13 basically what the examiner accepted was Finch's argument
12:31:16 that Hlavka doesn't teach using just basic poop.
12:31:20 Well, as you heard from Dr. Britton, using basic
12:31:25 poop was not an invention. That's what people had been
12:31:29 doing the entire time from the 1950s, was using uncultured
12:31:35 poop rather than trying to extract out and culture the
12:31:39 bacteria that are in it. Nobody was culturing the bacteria
12:31:43 at the time. So that was the state of the art, was to use
12:31:46 uncultured nonpathogenic material. Nonpathogenic just means
12:31:50 it doesn't have pathogens. You saw there was a reference in
12:31:54 Hlavka's screening, that's what you would do, you would
12:31:57 screen the pathogens.
12:31:58 So Dr. Britton said that can't be an invention,
12:32:01 that's obvious because that's what everybody had been doing
12:32:05 and what did Dr. Benson say in response to that? Did he
12:32:08 come in and tell you that Dr. Britton was wrong about that?
12:32:11 He didn't. He could have come and taken the witness stand
12:32:15 and said, I don't agree that people were using uncultured
12:32:19 stool for a long time, but he didn't come out and say that
12:32:23 and you can draw your open conclusions about why not. It's
12:32:28 a pretty common sense point. So that's just wrong.
12:32:31 And the next thing the examiner said is well,
12:32:35 this bacteria cryoprotectant mixture is stable during

long-term storage under freezing conditions. And remember, Finch had argued that means you got to be able to keep it for 12 months, so is that an invention, was that something that deserves a patent?

Remember, again, they had said that implies storing it for at least 12 months. And they said Hlavka is silent regarding any time frame for storage. So they said Hlavka tells you to freeze it but it doesn't tell you that you can keep it frozen for 12 months. Well, again, you heard Dr. Britton come in and testify to you about this. And what he explained is Hlavka says you should add a cryoprotectant and you should freeze it and the entire point of having a cryoprotectant is to keep it stable during long-term storage. The reason you've got a cryoprotectant in there is that a cryoprotectant protects from damage from freezing. Cryo is very cold. That's what it means. So that's the whole point of having a cryoprotectant and he said so that -- that's why it's there, you know, remember he said, you have these things stored in your freezer for like years, that's why you've got the cryoprotectant there. But there's actually another problem.

This is what Hlavka says. Hlavka, remember, earlier said, you add a cryoprotectant, you store it, you freeze it and it specifies the particular in order to maintain viability of the biota. The biota are the

bacteria, so you're freezing it to keep all of the little bacteria -- where did my REBYOTA go -- there, all the little bacteria in here sort of happy, you freeze it and it tells you what cryoprotectants you might want to use, glycol, glycerol, etc.

So did Borody make an invention that says okay, maybe Mr. Hlavka knew you froze it, maybe Mr. Hlavka knew you could have cryoprotectant in there, but he didn't tell you that you could store it for 12 months. Did he make that invention? So let's go look at what Dr. Borody says. It's not in there. All Dr. Borody says is, "You can add stabilizing agents like glycerol and in one embodiment, the stool is frozen." If anything Dr. Borody says less about freezing than Mr. Hlavka did. So they can't have it both ways, right.

If the invention requires that it be stable for 12 months and if this disclosure of freezing it and adding a cryoprotectant isn't good enough to tell you that's going to happen, if it's not good enough in Hlavka, it's not good enough in Borody either. If you need to say, you can keep it frozen for 12 months, and Dr. Borody didn't disclose that and he doesn't have support for that in his patent application, and it's invalid. And it's actually -- the 12 months isn't so important and if you can assume that once you add a stabilizing agent like glycerol and you freeze it,

12:35:48 you're going to be able to store it for 12 months, well,
12:35:53 then, it's obvious. If you would know that you can store
12:35:57 it, that a prolonged period of time is 12 months, then it's
12:36:03 obvious. They can't have it both ways. There is nothing
12:36:06 there in what Dr. Borody wrote that is an invention over and
12:36:13 above what Mr. Hlavka had already patented. And that's why
12:36:18 we think this patent is invalid.
12:36:21 And the examiner made a mistake in accepting
12:36:24 Finch's argument, because Dr. Borody didn't add anything to
12:36:28 the state of the art. And what you heard in that patent
12:36:31 video that started off this trial, is that's what you get
12:36:35 inventions for, you get inventions for things that move
12:36:38 science forward, you get inventions for things that add to
12:36:42 the state of the art and there is nothing in here that does
12:36:45 that over and above what we had already done.
12:36:48 What did Dr. Benson have to say about this? Did
12:36:52 he come in and tell you, oh, no, wait, I see something in
12:36:56 Borody that's different from what's in Hlavka? No. He
12:37:00 listened to Dr. Britton's testimony, sat through it, left,
12:37:06 hasn't come back. So I think that tells you something about
12:37:12 whether that testimony that we presented to you from
12:37:15 Dr. Borody was clear and convincing, because we think it
12:37:21 was. And if it was, that means that claim is invalid.
12:37:27 Means the examiner made a mistake in accepting Finch's
12:37:31 arguments and if you believe that is true, it is your duty

as jurors, following the law, to then find that claim to be invalid.

Now, there are a couple of additional requirements in some of these claims that we call dependent claims. One of them is that the system protects the fecal bacteria from destruction when the sealed container is frozen. That's the point of having a cryoprotectant. Hlavka talks about that. Dr. Britton explained that in his testimony. That's the point of having the cryoprotectant, it protects it. Their expert didn't come in and say that was wrong. Could have, but he didn't. That makes that claim invalid.

One of the claims has this requirement that there's an antioxidant and you heard it doesn't say the word antioxidant in Hlavka, that's true, but what it does say in Hlavka is, the gut microbiota is anaerobic. Anaerobic means it dies when it's exposed to oxygen.

And you heard Dr. Britton say well, look, when you're dealing with the gut microbiota and organisms that can die with exposure to air, it's not an inventive leap to think that you're going to use an antioxidant, because the purpose of an antioxidant is to protect from exposure to air. He came in and explained that, he said that's something you would want to do, that's obvious, of course, you would know how to do that if you were someone that

12:39:06 worked in the field. That's not an invention.

12:39:08 Did their expert come in and say that's wrong?
12:39:12 He didn't. Again, you can draw your own conclusions. But
12:39:16 we think that claim also is invalid because it doesn't add
12:39:21 anything to the work that we had already done. So for each
12:39:25 of those claims for the '080 patent, we think the correct
12:39:30 answer is "yes," Ferring has proven by clear and convincing
12:39:35 evidence that the claims are invalid as obvious.

12:39:39 Now, I want to talk about the '309, it's very
12:39:41 similar, mercifully, it's very similar. So why the '309
12:39:50 issue? The patent examiner gave her reasons for allowance
12:39:53 and it said there were three things. They said it was free
12:39:56 of rough particulate matter, it had the requirement of a
12:40:00 cryoprotectant and it's in a sealed container with flexible
12:40:03 tubing, which is to say it's in an enema bag. Those were
12:40:07 the things that the examiner thought were new and might be
12:40:09 an invention. So let's start with the sealed container
12:40:12 having a flexible tubing, right.

12:40:14 We know that's old, enema bags have been around
12:40:17 for decades. They're sealed containers, they have flexible
12:40:20 tubing. So whatever Dr. Borody invented in March of 2011,
12:40:25 it was not using an enema bag and you saw that the Hlavka
12:40:29 patent specifically talked about NMP anemic route of
12:40:32 administration, about using enemas. So that can't be the
12:40:36 invention.

12:40:37 What about a cryoprotectant? That's in Hlavka
12:40:39 too, right, Hlavka specifically talks about a cryoprotectant
12:40:43 so, again, whatever Dr. Borody invented, it can't be a
12:40:47 cryoprotectant. So what's left? Being free of rough
12:40:49 particulate matter.
12:40:50 So this is interesting, because if what it means
12:40:54 to be free of rough particulate matter is that you actually
12:40:59 separate out all of the bacteria from all of the rough
12:41:05 particulate matter. If I get rid of -- I think I'm actually
12:41:11 supposed to get rid of the orange things but whatever. If I
12:41:14 got rid of all of the orange things and the only thing that
12:41:18 was left were the blue things and if I had in here a
12:41:21 composition that was just bacteria and had no rough
12:41:24 particulate matter, sure, I'm not aware of anyone who did
12:41:30 that before 2011, that would be fair and I think that would
12:41:34 be a valid patent if that's what that means.
12:41:39 But Finch is in here telling you, well, free of
12:41:44 rough particulate matter doesn't actually mean free of rough
12:41:48 particulate matter, it just means we've taken out a little
12:41:51 bit of it. That was definitely not an invention, because
12:41:55 people had been doing that for a long time.
12:41:59 Do you remember how people did FMT back in the
12:42:03 '50s, '60s, '70s, '80s, they used a blender and then they
12:42:07 used a tea strainer or a coffee strainer. You know what
12:42:11 happens if you put stuff in a coffee filter, right, you get

your coffee and chunky stuff stays behind. So the idea of getting rid of some of the chunky stuff, that was not new, that was not Dr. Borody's invention. If he actually was talking about true separation, fine, don't invalidate his patent, that's fair. But if you were to accept Finch's position, that that patent only requires that you get rid of a little bit of the chunky stuff, some of it, that was not the invention because people had been doing that forever.

And that's what Dr. Britton explained. He said, "Hlavka recognizes samples are homogenized. They are filtered." It's in Hlavka. They are filtered. Why do you filter? You do it to get rid of solid chunks that would clog the enema bags. So if that's enough, if that's all the patent is talking about, that was absolutely in the prior art. It was in our earlier patent. Getting rid of big, chunky stuff can't be the invention here.

So they can't have it both ways, right? They can't say on the one hand, "Oh, we invented something that just requires getting rid of big, chunky stuff," but on the other hand, "Oh, no, no, no, you know, you infringe because you've got these macroscopic particles even though we have these macroscopic particles in here along with the bacteria." They can't have it both ways.

So that is why, if you accept their position on infringement, if you say it's good enough to get rid of a

few things, even if there's a lot of macroscopic matter that remains behind, they didn't make new inventions. People were using coffee filters in, like, the 1980s, if not the 1950s. So I want you to hold them to their position. They need to be consistent in what they are saying this patent is about because the idea of straining, that's all that is required. That was already in our patent, and that would make the '309 patent invalid.

Now, there's a couple of additional requirements. One of them is PEG, polyethylene glycol. The patent talks about glycol. You've heard from Dr. Park. PEG is a glycol. That means it discloses it. It discloses glycols. It says it. So that can't be the invention. That would be invalid.

And note, the patent examiner, they didn't point you to the examiner saying, "Oh, the invention is, you know, PEG," or, "The invention is an antioxidant." The examiner thought the invention was separated, truly separated, not that kind of separating, but, you know the full, actual separating that we don't do. But it didn't say these things were inventive, and that makes a lot of sense because as we've seen, having an antioxidant is the most obvious thing if you're dealing with something that is going to perish in the presence of oxygen.

Again, Dr. Britton explained this. He walked

12:45:26 through those claims. He explained that they were invalid
12:45:30 as obvious in view of these disclosures in Hlavka. And,
12:45:34 once again, what did their expert have to say in response?
12:45:38 Did he come in and say, "Oh, no, there really is an
12:45:41 invention here about about separating. The examiner got it
12:45:44 right. These other things are important"? He didn't come
12:45:46 in and say any of those things.
12:45:49 So, again, we met our burden of proof. We
12:45:53 brought you our proof in the form of our experts. We put it
12:45:57 on the table. They testified about it. We explained why we
12:46:01 think it's clear and convincing evidence. And their experts
12:46:05 did not come in here and tell you that that was wrong.
12:46:10 So for both questions for the '309 patent as
12:46:14 well, we think the correct answer is that they are also
12:46:18 invalid.
12:46:20 That brings me to this question of willfulness,
12:46:23 of willful infringement. So this is only a relevant
12:46:26 question if we infringe. If we don't infringe and if the
12:46:29 patents are invalid, you get to stop relative to this. You
12:46:32 can ignore everything that I'm about to say because it
12:46:35 doesn't matter to your decision, but I want to talk about it
12:46:39 because there's a couple things that I think are really
12:46:41 important because it's been suggested somehow that Lee
12:46:44 Jones, you know, blew the whistle, that she was there
12:46:47 saying, "Oh, my God, we infringed."

12:46:49 There is no evidence of that. You heard her
12:46:52 testify. She didn't say, "Oh, I was worried that we were
12:46:55 infringing." She testified the opposite. She said she was
12:46:57 confident that there was not a problem. And, in fact, you
12:47:00 heard that when Ferring acquired Rebiotix, it is true the
12:47:04 question of these patents came up because everyone in this
12:47:07 field is reading each other's patents. That's what you do
12:47:11 and figuring out and looking at what other people are doing
12:47:13 and they wanted to make sure there was not a problem.
12:47:17 So what do we do? This is TX-3768. You can
12:47:21 read it. You're going to have it, but they did testing.
12:47:25 They got a bag of RBX-2660. That was what REBYOTA was
12:47:30 called at the time. They ran it through a sieve. They did
12:47:33 the experiment that Dr. Johnson did. And they said the
12:47:37 particles wouldn't go through even a 600 micron screen. And
you got pictures of the testing they did. They talked about
it.
12:47:42 This was the claim. It needs to comprise no
12:47:46 particle having a size of greater than .5 millimeters.
12:47:47 We've done testing. That's what the claim was at the time.
12:47:50 We found this product does contain particles. They're
12:47:53 bigger, they're here, they're sitting on the filter, they
12:47:56 did the experiment at the time to satisfy themselves that
12:47:58 they did not have an infringement problem.
12:48:02 Now, I want to note, you're stuck with the

12:48:04 claims based on what you understand them to be at the time,
12:48:07 right? And I told you claims change over time. So you can
12:48:11 only look at the disclosure of the patents as it exists, and
12:48:15 it's sort of an interesting story in the context of this
12:48:19 case.
12:48:19 And I just want to give you one example. So
12:48:21 Ms. Jones filed her provisional application in June of 2013.
12:48:25 You're going to have all these patents, and you can look at
12:48:28 them. And you'll see on the first page here, if you want to
12:48:32 sort of check what the dates are, it's got the title, it's
12:48:36 got the applicant, the inventor, and then here, it says --
12:48:40 it gives you related U.S. applications here and it gives you
12:48:45 prior publication data and it tells you when the thing was
12:48:50 filed. And you can look and you can see what the
12:48:55 original -- here's the chain of application -- data was,
12:48:58 what the first filing date was. And here on the example of
12:49:02 this patent -- this is the '080 -- it's down here, and it
12:49:04 says, "Provisional application filed March 7th, 2011." So
12:49:09 that earliest date, that becomes what we call their priority
12:49:12 date. That's the earliest they can go in saying they made
12:49:15 the invention.
12:49:16 So Ms. Jones -- you'll be able to check this
12:49:18 yourself -- she files her provisional on June 2013. Finch
12:49:22 is then incorporated in November of 2014. Her patent
12:49:25 application then publishes. They become -- you heard that

12:49:28 patent applications become public, and that's part of the
12:49:32 patent bargain, right? Part of the patent bargain is you
12:49:35 have to tell the world about your invention so people can
12:49:35 learn from it. There's nothing wrong with reading patents,
12:49:38 learning from them. That's the point.
12:49:40 And so one of the things it talked about was
12:49:43 storing the REBYOTA at minus 80 for more than 12 months and
12:49:48 that it was stable during this long-term storage. That
12:49:51 became public. Finch then saw the results of Rebiotix in
12:49:56 terms of the trials and things we were doing. In 2016, our
12:49:59 patent issued. And then in May of 2022, Finch files this
12:50:07 patent application that results in the '080 patent.
12:50:10 Now, I want to be clear. It's a little
12:50:13 confusing because you're thinking to yourself, well, wait a
12:50:16 minute, didn't they file it back in 2011? They filed a
12:50:20 provisional here. They then filed a patent application, but
12:50:22 then you keep being able to file what are called
12:50:24 continuations, all of which go back and get the benefit of
12:50:29 this date. So you basically keep making new filings with
12:50:34 the Patent Office, got the same disclosure, but it's in a
12:50:37 new filing. When you make a filing, you have to pay new
12:50:40 fees. That's probably why you have to keep making new
filings, right, to keep getting fees.
12:50:41 But they make a new filing. So they make a
12:50:44 filing in May of 2022 based off of this 2011 disclosure, and

12:50:50 what do they do? They now seek claims for the first time to
12:50:55 something that is stable during long-term storage when
12:51:00 frozen.
12:51:02 So if you're thinking about whether you've got a
12:51:06 problem from a willfulness point of view, you're probably
12:51:10 not thinking that it is going to be a problem with respect
12:51:13 to storage, long-term storage at minus 80 degrees if you're
12:51:18 thinking about this problem in 2014, 2015, 2016 or 2017. So
12:51:23 I think it's important to understand the timing. When you
12:51:27 think about people's state of mind and what was the evidence
12:51:30 that was in the record that was actually in front of them
12:51:32 that they could look at for what people had claimed to have
invented.
12:51:38 So for a lot of reasons, I think the answer to
12:51:42 this question -- and I hope you don't get to this question.
12:51:42 I don't think you should, but if you were to get to this
12:51:45 question, I think that the answer to this question ought to
12:51:47 be no because Ms. Jones and her colleagues at Rebiotix and
12:51:54 the people had Ferring acted in good faith. They did the
12:51:57 tests, they looked at the patents and they believed exactly
12:52:00 what I am telling you here today, which is there is no
12:52:04 infringement of any valid claim because we don't infringe
12:52:07 the University of Minnesota patent and because this Borody
12:52:11 disclosure is not any different from the work that
12:52:14 Mr. Hlavka already had done and we were relying on.

12:52:18 Now, I want to touch very briefly on this
12:52:21 question of damages. And, again, I am hoping that you can
12:52:24 ignore everything that I'm about to say because it's not
12:52:27 going to matter. But I do want to respond to it because
12:52:30 they are asking for a lot of money. And I've got to talk
12:52:36 about that.
12:52:37 So what do you get if you infringe a patent?
12:52:40 You get a reasonable royalty. That's what you've heard.
12:52:43 And you've heard that it's what someone would pay in a
12:52:46 hypothetical negotiation for a license to the patent.
12:52:51 So you heard Mr. Kidder. He explained how this
12:52:54 works. And the experts agree on the basic paradigm about
12:53:00 how you do the analysis. You start with a comparable. He
12:53:03 thought the best comparable is University of Minnesota
12:53:05 agreement. I'll talk about why. And it was at 3%, and he
12:53:09 made adjustments, adjusting upwards for reasons that he
12:53:13 explained, University license, among other reasons, and he
12:53:16 said a reasonable royalty would be 5.5% of our sales.
Why did he start with the University of
12:53:21 Minnesota license as a license for these patents? It was a
12:53:24 number that the University of Minnesota agreed to. They're
12:53:27 one of the plaintiffs, and the best evidence is what
12:53:30 somebody -- of what somebody would charge for something is
12:53:32 what they did charge for something. Right? That's the best
12:53:35 evidence of what that thing is actually worth.

12:53:37 And then he did a reasonableness check, and he
12:53:41 said, "All right. How does that compare to the University
12:53:44 of Minnesota, and how does that compare to every other
12:53:46 finance agreement that Finch has entered into?"
12:53:48 Now, there were a couple licenses with
12:53:51 OpenBiome. Sure. It's a nonprofit, but still, Finch was
12:53:55 willing to license, you know, a company to make an
12:53:58 enema-based product at a rate.
12:54:01 There was the collaboration with Takeda to be
12:54:04 sure. It had the potential for big milestones because it
12:54:08 was a product development agreement, the royalty rate for
12:54:12 patents of 3%, and a University of Arizona license agreement
12:54:16 and said, "This looks pretty reasonable." And if you apply
12:54:20 that percentage to our total sales to date, all of the money
12:54:23 that Ferring has made from selling REBYOTA, that's $815,000.
12:54:28 Now, you heard that the University of Minnesota
12:54:30 license agreement has an upfront payment of $145,000, and it
12:54:35 does. And you also heard Mr. Kidder say he doesn't think
12:54:40 here there would have been any upfront payment because, in
12:54:43 the case of that license agreement, the University of
12:54:46 Minnesota didn't know it was going to make anything because
12:54:48 a product was years and years and years away.
12:54:50 And you heard most products fail. So odds are
12:54:54 they were going to license these patents and get nothing in
12:55:00 terms of running royalties because you only get those

12:55:02 1 royalties if there's a sale. If there's no product, there's
12:55:05 2 no sale. If there's no sale, there's no royalty. So it was
12:55:08 3 entirely likely that $145,000 was going to be it. Whereas
12:55:13 4 in the negotiation, this hypothetical negotiation between us
12:55:16 5 and Finch, we're about to start selling REBYOTA. So they
12:55:20 6 know they're going to get something because there's actually
12:55:22 7 a product to sell.
12:55:26 8 So our expert, using the University of Minnesota
12:55:28 9 license, said $815,000. Obviously, the experts came in here
12:55:33 10 and presented to you wildly differing views about what the
12:55:38 11 number should be. We think Mr. Malackowski's number is just
12:55:44 12 fundamentally wrong here. And we think that's true for a
12:55:48 13 bunch of reasons.
12:55:50 14 Reason number 1, he didn't start off with a
12:55:53 15 patent license. He essentially ignored the patent license
12:55:57 16 to the actual patents-at-issue in this case. And instead,
12:56:00 17 he relied on a product license to a product that had been
12:56:05 18 developed.
12:56:07 19 Now, what were the patent -- well, were patents
12:56:10 20 included as part of that bundle? They were. We know
12:56:14 21 nothing about those patents because all the information
12:56:16 22 about those patents was redacted. It was whited out from
12:56:20 23 the agreement. So if you wanted to compare how those
12:56:23 24 patents compare to Dr. Borody's patents or the University of
12:56:27 25 Minnesota patents, good luck. There's nothing to rely on.

12:56:29 There's literally no way to make that comparison because we
12:56:33 don't know what they are.
12:56:34 And Mr. Malackowski himself agreed that a
12:56:38 collaboration agreement and a bare patent license are
12:56:42 fundamentally different agreements. You may wonder why he
12:56:46 was willing to agree to that because he said it before, but
12:56:49 he agreed to that, right? They are fundamentally different
12:56:52 agreements. And that's because they are because you heard
12:56:57 Mr. Kidder explain a product sale is like the sale of an
12:57:02 apartment building. You are buying a product with all of
12:57:06 the rights that go with it, right, the product itself.
12:57:09 And a patent license is like renting an
12:57:14 apartment inside that apartment building. No big surprise
12:57:17 that the economics of buying an apartment building and the
12:57:21 economics of renting an apartment are very different. And
12:57:26 Mr. Malackowski admitted that none of the licenses that he
12:57:29 relies on are just patent licenses. Every single license he
12:57:34 relied on was a product transaction. And if you ask
12:57:39 yourself, it makes sense because they are so different, he
12:57:48 didn't want to include a patent license because they would
12:57:52 mess up his numbers because they are a lot less.
12:57:54 Now, the Court has instructed you that
12:57:56 damages -- the damages reward has to reflect the portion of
12:58:00 the royalty attributable to the patented compositions or
12:58:03 methods. In other words, your damages award must reflect

12:58:08 the value you find attributable to the asserted claims. In
12:58:11 other words, the thing that you're trying to do and that the
12:58:14 damages experts are supposed to do is figure out how much
12:58:18 are these claims worth, right? How much are these specific
12:58:21 claims worth?
12:58:22 Dr. Malackowski -- or Mr. Malackowski, sorry, he
12:58:25 didn't do that. He didn't even try to do that. Now, he
12:58:28 admitted that is the test, that's the test. You're valuing
12:58:33 the incremental value that patented invention has over the
12:58:37 prior art. What does that mean? Take Borody, how much does
12:58:41 Borody add to what Hlavka did? That's what you're trying to
12:58:45 put a value on and a number on.
12:58:47 What's the difference? He didn't try to do that
12:58:50 because he was making an assumption. This is really
12:58:55 important. I asked Mr. Malackowski about something that he
12:59:00 was told by Dr. Benson. I said, in fact, what Dr. Benson
12:59:07 told you -- remember, Dr. Benson is their technical expert,
12:59:09 was that in view of Finch's patent portfolio, it would be
12:59:13 impossible to develop a product using fecal transplant
12:59:19 technology directed to C. diff. Words to that effect? Yes.
12:59:24 A remarkable, precise answer from Mr. Malackowski. Yes.
12:59:26 So what is he saying? Dr. Benson told him there
12:59:29 is no way to have an FMT product directed to C. diff without
12:59:33 using these inventions. It's not that surprising, I think,
12:59:39 that Dr. Benson said that is not what I said, right?

12:59:42 Because he was asked, are you telling me it would be
12:59:46 impossible to develop any product in this field without
12:59:48 using the asserted patents? No, no.
12:59:50 And you didn't tell that to Finch's expert,
12:59:52 Malackowski, right? I don't believe so, no.
12:59:54 I mean, no surprise that Dr. Benson said that
12:59:57 because that's nuts, right? FMT has been around since at
13:00:01 least the 1950s. You don't need 2011 technology to do FMT.
13:00:08 It's been around forever, that can't be right. But that was
13:00:12 the cornerstone assumption that Mr. Malackowski made and the
13:00:17 reason that he was able to say, I don't need to look at the
13:00:20 prior art and stuff because these patents are so
13:00:23 foundational and fundamental to FMT that you can't have a
13:00:27 product without them. That was just wrong and it is
13:00:30 inconsistent with the Court's jury instructions because the
13:00:33 Court has said that you can award damages based only on
13:00:36 royalties that are directly attributable to the value of the
13:00:39 patented technology, not what people had done before.
13:00:42 You can't charge for the fact that FMT works.
13:00:45 You can't charge for Hlavka. You can't charge for other
13:00:49 prior art. You can only charge for what this added and
13:00:56 Finch has no evidence, no proof. Again, this is something
13:01:00 on which they bear the burden of proof of Mr. Malackowski's
13:01:04 assumption. It was contradicted by Dr. Benson. There is no
13:01:08 evidence that PEG is some critical thing that you have to

13:01:12 have. There's no evidence that being able to have an FMT
13:01:16 product depends on having a .5 millimeter sieve, that you
13:01:20 can't have a product without it. There's no evidence that
13:01:22 you have to have an antioxidant or you have to separate
13:01:25 rough particulate matter, and that all of those are
13:01:28 essential ingredients in a successful product. There's no
13:01:32 reason to think that and that means that Mr. Malackowski's
13:01:36 whole opinion collapses because that was the foundation on
13:01:39 which he was testifying.

13:01:42 Mr. Malackowski's third mistake, relying on
13:01:45 projections rather than sales when he had the actual numbers
13:01:48 and he just ignored them. Now, you just heard an effort to
13:01:51 say, well, maybe sales were off to a slightly slower start
13:01:55 than they were expecting, but it's not really that big a
13:01:58 deal. The numbers show it is a real big deal.

13:02:01 These are what the projections were through
13:02:03 August of 2024. Those are the actual sales. There is a
13:02:08 huge discrepancy. So if we get to damages, we're supposed
13:02:11 to be talking about what we owe for the infringement that
13:02:13 has happened, not what might happen in the future. You pay
13:02:17 for that in the future. But the infringement that has
13:02:20 happened.

13:02:20 The infringement that has happened is
13:02:23 $14 million worth of sales. They're trying to keep talking
13:02:26 about billions and hundreds of millions of really large

numbers in the hopes that, you know, if you talk about really large numbers often enough, then you think that really large numbers are appropriate. But the reality is $14 million in actual sales.

If you have the actuals and you're Mr. Malackowski, why don't you use them, right? I want you to think about that.

Mr. Malackowski's next mistake, he didn't do any reasonableness check. He didn't really sit here and say, oh, why would it be a 30% royalty if the University of Minnesota license agreement is only 3. Now, you just heard, well, it looks reasonable in light of the Nestlé-Seres agreement at 50%. That's not a 50% royalty, that is a 50% profit split. That is two companies who are getting together as commercial partners to sell a product and they're saying we're going to split the profits of that product 50/50. That has nothing to do with what you would pay for a license to any patent, let alone these. And that is how Mr. Malackowski is able to say, even though we have only sold $14.8 million of product, you should pay $55 million in fees to them.

In other words, that we should pay almost four times as much as we have made total in royalty fees, right? That's like you get a paycheck and you get asked for, like, 4x. That's insane and that is not how patent damages work.

13:04:04 Now, I'll note I asked Mr. Malackowski's some
13:04:07 questions about his testimony in a prior case because the
13:04:10 fact that it's insane is reflected in his opinion in this
13:04:14 other case. Here, he's on the plaintiff's side, he says
13:04:17 $14.8 million in sales, $54 million in damage. When he was
13:04:21 a defense expert for the $377 million worth of sales in a
13:04:26 pharmaceutical case about a melanoma, a cancer drug, he said
13:04:31 a reasonable royalty was $2 million. That's a lot more in
13:04:35 line with reality than what he's proposing here.
13:04:40 Now, how does Mr. Malackowski try to justify
13:04:43 this? You've heard this theme running throughout Finch's
13:04:47 case that they failed and they were so close and that it was
13:04:50 at least in part somehow our fault. So let's just look at
13:04:56 the -- take a look at the evidence that came in about why
13:04:59 Finch actually failed. I guess we can parse words, but I
13:05:04 would call several hundred million dollars an investment and
13:05:07 no product at the end of it, a failure. I don't mean that
13:05:10 to cast aspersions. I think the guys who founded Finch were
good guys who were trying to do good things, but I don't
13:05:15 think that there is any universe where you can call that a
13:05:16 success.
13:05:18 So why, right? Well, Mr. Burgess gave some
13:05:22 answers. Startups are risky, most companies don't make it,
13:05:26 most drugs aren't approved by the FDA. It's a really big
13:05:30 deal to develop a drug that actually gets approval by the

13:05:33 Food and Drug Administration. You heard that most of them
13:05:36 fail, most of them don't. Big investment, big risks. Big
13:05:42 reward if you're successful, that's true. But big
13:05:44 investment and big risk, and most companies are not
13:05:47 successful.
13:05:47 And Finch was founded after Seres and Rebiotix
13:05:52 had already entered the field in 2010 and 2011,
13:05:55 respectively. In fact, they didn't even start OpenBiome
13:05:59 until after that. So they were coming in already behind.
13:06:03 Finch is incorporated in 2014 and you'll remember, it starts
13:06:06 out life as a software company and then they decide they're
13:06:11 going to pivot and try to make a drug. They do that after
13:06:14 they learned that REBYOTA's was trying to develop a drug.
13:06:17 So, again they know they're behind, they know Rebiotix is
13:06:20 out in front. They weren't worried about it. They weren't
13:06:23 worried about it because they thought that Rebiotix's enema
13:06:27 product was fundamentally challenged given difficulties in
13:06:31 targeting product delivery and ensuring retention. They
19 thought enema is a bad idea, so they decided to develop a
13:06:35 pill and they weren't worried about competition from an
13:06:38 enema product because they thought it was going to fail and
13:06:40 that's why they said internally it's not a significant
13:06:43 competitor to CP101, that was their pill product, given its
13:06:47 enema route of administration. And, in fact, when they saw
13:06:52 our data, they thought it was great. They thought it was an

13:06:55 ideal outcome, validation for the field because it was
13:06:59 showing generally that you had had an FMT product, but great
13:07:00 for them because they were differentiated, they had a
13:07:05 different product because they had a pill, and they thought
13:07:08 their product was better. That's in May of 2021.
13:07:11 Now, again, I want to note, their pill product
13:07:16 to treat C. diff was not the only product they had that
13:07:19 failed. They tried to go after a lot of different things at
13:07:24 the same time. They spread their effort and their attention
13:07:28 and their money around. They all failed. They had a
13:07:31 partnership with Takeda, that failed.
13:07:34 Rebiotix tried to do one thing and one thing
13:07:37 only, make this. This was it. Every person at the company,
13:07:42 all of the money, all of the effort was this, and that was
13:07:46 it. These guys tried to do a whole bunch of stuff and
13:07:51 ultimately, it turned out that none of it was successful.
13:07:55 They also ran into some challenges with the FDA.
13:08:00 Interacting with FDA is hard. It's complicated,
13:08:04 it is hard, it is a difficult regulatory environment. You
13:08:08 need to know what you're doing, you need to get stuff right.
13:08:11 That's why one of the first things that Lee Jones did at the
13:08:13 University of Minnesota was introduce Dr. Khoruts and Dr.
13:08:16 Sadowsky to experts in FDA regulatory approval. It's really
13:08:20 hard.
13:08:20 Finch had a lot of problems. There was an

13:08:23 issue, and you heard testimony about this, where two
13:08:26 patients died after using OpenBiome materials, clinical
13:08:30 holds got put in place in March of 2020 -- it was COVID --
13:08:35 for both of their products. Finch kept using OpenBiome
13:08:39 materials. They said that they were operationally
13:08:39 constrained, they were burning cash. They, then, got put on
13:08:43 another clinical hold by the FDA for their CP101 pill
13:08:47 product. That led them to having to reduce their work
13:08:51 force. Takeda canceled their agreement for the other
13:08:54 indications and just having invested money, just pulled the
13:08:57 plug on the whole thing. They started dosing for CP101 in
13:09:00 October of 2022, then they discontinued one of their other
13:09:05 products and then in January of 2023, they discontinued
13:09:08 CP101. I would suggest to you it's not that hard to figure
13:09:12 out what happened and it wasn't our fault.

13:09:19 And brings me back to Lee Jones and the
13:09:22 University of Minnesota and her long relationship with the
13:09:28 University. You heard she went to college there, she got
13:09:31 her MBA there. She's been involved with the University both
13:09:36 before, with the Diabetes Institute and since. And when
13:09:43 Rebiotix got sold to Ferring, it was big news in Minnesota.
13:09:46 That was a big deal. You've got a company that's getting
13:09:49 acquired.

13:09:50 What did the University say then? Did they say
13:09:53 you did something wrong in starting this company? No. Did

13:09:57 they say you've got a product, you must be infringing our
13:10:00 patents? No. They said, "Congratulations on the exit. I'm
13:10:05 sure this is great news to all involved in the company, it
13:10:09 is also great news for the community," the community of
13:10:11 which the University of Minnesota and Lee Jones are both a
13:10:14 part. And I would suggest to you that that was true.
13:10:16 And, in fact, Russ Straate in May of 2021 asked
13:10:22 Ms. Jones to come in and lead out a new company to be
13:10:27 founded on University of Minnesota technology and to serve
13:10:31 as the CEO. And then in 2020, the University of Minnesota
13:10:40 gave her an award as entrepreneur of the year to recognize
13:10:48 her entrepreneurial success and to recognize her
13:10:50 significance contributions to the University. And I want to
13:10:51 read this, "You would be hard pressed to find anyone that
13:10:54 has been more involved in supporting the entrepreneurial
13:10:58 community at the University of Minnesota. Lee is the
13:11:01 consummate role model for our students and alumni. While
13:11:02 building two highly successful healthcare companies, she has
13:11:06 continuously given back by inspiring and supporting the next
13:11:10 generation of entrepreneurs."
13:11:13 And I would suggest to you that is not an easy
13:11:16 thing to do. Finch got a lot of money. They were not able
13:11:21 to do it. She pulled together a small group of investors,
13:11:26 she started a company, she hired the first employees, they
13:11:29 developed a new and different process, and that led to the

13:11:35 first FDA approval of this entire category of drugs. This
13:11:45 new product that, for the first time, gave patients an
13:11:49 FDA-approved safe and effective treatment for C. diff.
13:11:55 That's hard to do, most companies can't do it, and she and
13:12:02 this group of people did.
13:12:04 She doesn't work for Ferring anymore. Courtney
13:12:08 Jones doesn't work for Ferring anymore. But they came here
13:12:13 to testify because this is important to them and she wants
13:12:17 to clear her name because I would suggest to you that her
13:12:21 name has been dragged through the mud and this is important
13:12:24 to her.
13:12:26 So I would ask you in this case to do just that
13:12:32 and we would ask you to render a verdict for the defense.
13:12:36 And I want to thank you very much for the time
13:12:40 and attention and thoughtfulness with which you have
13:12:48 approached this case. Thank you.
13:12:51 THE COURT: Thank you, counsel.
13:12:52 Could I see counsel at sidebar briefly?
13:13:14 (Sidebar discussion.)
13:13:14 THE COURT: Well, the first question I had
13:13:15 was -- I wanted to address the curative instruction.
13:13:18 Are we withdrawing that?
13:13:20 MS. DURIE: Yeah. I'll withdraw the question.
13:13:21 THE COURT: The second thing I wanted to address
13:13:23 is that Finch has five minutes, exactly, left.

13:13:28 MR. DE VRIES: That's what I was going to say, too. Just wanted to confirm.

13:13:33 THE COURT: Yeah.

13:13:49 (Sidebar discussion concluded.)

13:13:49 MR. DE VRIES: Your Honor, may I proceed?

THE COURT: Yes.

13:13:50 MR. DE VRIES: Thank you.

13:13:51 I'm not going to have time to respond to most of what you heard over the last hour and 50 minutes, you're going to have to rely on your evidence and your common sense. I'd like to address a few points.

13:14:03 Could I get slide 4.

13:14:04 They don't have an answer for this. This doesn't say we reviewed Hamilton 2012 and we thought about some other things and went in a different direction. It says the manufacturing process for RBX-2660 was derived from Hamilton 2012.

13:14:20 Slide 15. They didn't address this at all during their presentation. This is Mike Berman talking about reviewing the University patent application with Lee Jones when they were founding Rebiotix. They have no answer.

13:14:36 Slide 91. They suggested that Dr. Benson didn't do any testing. That's not true. He did. He showed it to you. He also analyzed their testing. He explained why

13:14:49 under all the testing, there was infringement that clearly
13:14:54 established that REBYOTA meets the claims and nothing about
13:14:59 a bag of REBYOTA that's been sitting out of the refrigerator
13:15:03 for hours and has been handled, it is going to change that,
13:15:07 even if the microscopic particles that went through the .5
13:15:12 millimeter pores have clumped together after all of that
13:15:16 handling and sitting around. Kind of like the prune
13:15:20 experiment, it's not relevant.
13:15:22 Slide 128, please. They spent a lot of time
13:15:26 talking about, that we didn't bring experts to respond to
13:15:31 their invalidity arguments. And I think what that argument
13:15:34 is intended to suggest is that although they acknowledged
13:15:40 they have a clear and convincing burden in taking away the
13:15:44 patents from the University and from Finch, that because we
13:15:49 didn't have experts come and bring Dr. Benson back for
13:15:52 another round of examination, that there was some problem
13:15:55 with that, that means we agree. It is the opposite. I
13:16:00 showed you this during my opening presentation. Their own
13:16:04 experts under the -- being subjected to our
13:16:07 cross-examination, admitted key things that are
13:16:11 fundamentally contradictory to their invalidity arguments.
13:16:16 They admitted, Dr. Treangen admitted that
13:16:19 their -- that when he sees this figure, he knows that
13:16:23 they're based on underlying tables of data and numbers.
13:16:26 With that admission, we had no need to take any more of your

time to bring Dr. Benson back or anyone else. They had failed their burden of proof and that was it.

If you go to slide 109, it's the same for Dr. Britton. I asked him a number of questions. He admitted, Hlavka doesn't teach antioxidant. He didn't show any other prior art reference that does. Hlavka doesn't say polyethylene glycol. When their invalidity case is over, then there's no need to take up more of your time. We've taken up enough of your time and now it's time for you all to have the opportunity to decide what you think of all the evidence. This will be your decision, it is your choice, not the lawyers.

Could I please get slide 161? As I expected might happen, we heard even new arguments during the course of the closing arguments that we never really saw, even during the trial, I never heard anyone talking about this and there was a lot of new information that you've never seen provided about Lee Jones' patents and the Hlavka patent. Her Honor has instructed you, that whether Ferring has patents or patent applications and whether any of them cover REBYOTA, should not be considered in your determination of whether Ferring infringes, it's irrelevant.

Slide 143, let me end here. Got one more minute. Ferring Pharmaceuticals, they didn't bring anyone who currently works at the company, not one person to answer

13:18:03 our questions live under oath about why they launched
13:18:06 REBYOTA in January of 2023.
13:18:09 Next slide. They've tried to suggest that we're
13:18:12 attacking Lee Jones. That is not true. They're the
13:18:16 defendant. They didn't bring anyone to come for you to see
13:18:23 live and answer questions.
13:18:24 Next slide, please. The witnesses that they
13:18:26 brought haven't been affiliated with them for years. Mike
13:18:29 Berman, no involvement after 2018, Lee Jones stopped working
13:18:33 for Ferring in 2022, Courtney Jones, she was laid off. No
13:18:38 one from the company who's the actual defendant is here and
13:18:40 the misdirection about Lee Jones means nothing in terms of
13:18:44 whether they infringed.
13:18:46 Next slide. The last thing I'll say is, so just
13:18:51 to remind you that instead of coming to face you all live,
13:18:55 what did they do instead? Did they ask for a royalty? Did
13:18:58 they pay anything? No. They threatened and bullied a
13:19:02 public University.
13:19:02 With that, I'm done. I wish you the best of
13:19:05 luck in your deliberation and I thank you again on behalf of
13:19:10 our clients.
13:19:10 THE COURT: Thank you, Counsel.
13:19:12 Ladies and gentlemen, we'll finish with the last
13:19:14 jury instruction, it's 11.3. Duty to deliberate.
13:19:18 Now that all the evidence is in and the

13:19:19 arguments are completed, you are free to talk about the case
13:19:23 in the jury room. In fact, it is your duty to talk with
13:19:26 each other about the evidence and to make every reasonable
13:19:30 effort you can to reach unanimous agreement.
13:19:32 Talk with each other, listen carefully and
13:19:35 respectfully to each other's views and keep an open mind as
13:19:39 you listen to what your fellow jurors have to say. Try your
13:19:43 best to work out your differences. Do not hesitate to
13:19:47 change your mind if you're convinced that the other jurors
13:19:50 are right and that your original position was wrong but do
13:19:54 not ever change your mind just because other jurors see
13:19:58 things differently or just to get the case over with.
13:20:01 In the end, your vote must be exactly that, your
13:20:04 own vote. It is important for you to reach unanimous
13:20:07 agreement but only if you can do so honestly and in good
13:20:11 conscience. No one will be allowed to hear your discussions
13:20:15 in the jury room and no record will be made of what you say.
13:20:18 So you should all feel free to speak your mind. Listen
13:20:22 carefully to what the other jurors have to say and then
decide for yourself.
13:20:26 And at this time, I am going to ask my courtroom
13:20:26 deputy to hand out the verdict forms. Thank you and I'll
13:20:46 ask the Court security officer to come forward.
13:20:58 COURT CLERK: Please raise your right hand.
13:21:01 COURT SECURITY OFFICER, having been duly sworn,

was examined and testified as follows:

COURT SECURITY OFFICER: I do.

COURT CLERK: Thank you.

THE COURT: All right. Mr. Kohler, let's take the jury back to the jury room.

(Jury exits.)

THE COURT: All right. Please be seated. All right. I'd like to ask each side to make sure that we have cell phone numbers where we can reach you in case the jury has a question or we get a verdict.

Is there anything else we need before we recess?

MR. DE VRIES: Not for the University or Finch.

MS. DURIE: No, Your Honor.

THE COURT: All right. Thanks very much, everyone. We'll be in recess.

(A brief recess was taken.)

COURT CLERK: All rise.

THE COURT: Please be seated. I understand that we have a verdict. I'll ask my courtroom deputy to bring out the jury.

(Jury enters.)

THE COURT: Please be seated. All right. Ladies and gentlemen of the jury, I understand that you have a verdict. Can the foreperson indicate whether or not that's correct?

16:22:33 JURY FOREPERSON: Yes.

16:22:36 THE COURT: Okay. I'll ask my courtroom deputy to take the verdict from the foreperson.

16:22:51 Mr. Kohler, could you please read the verdict.

16:23:27 COURT CLERK: Yes.

16:23:28 Question 1. Do you find that UMN/Finch has proven by the preponderance of the evidence that Ferring literally infringed the following claims of the following patents:

16:23:37 '914 patent, Claim 7? Yes.

16:23:40 '309 patent, Claim 16? Yes.

16:23:43 '309 patent, Claim 21? Yes.

16:23:47 '080 patent, Claim 2? Yes.

16:23:51 '080 patent, Claim 9? Yes.

16:23:55 Question 3. Do you find that UMN/Finch has proven pie a preponderance of the evidence that any infringement by Ferring of the following patents was willful?

16:24:04 '914 patent? Yes.

16:24:08 '309 patent? Yes.

16:24:10 '080 patent? Yes.

16:24:13 Question 4. Do you find that Ferring has proven by clear and convincing evidence that the following claims of the following patents are invalid as obvious:

16:24:22 '309 patent, Claim 16? No.

'309 patent, Claim 21? Yes.

'080 patent, Claim 2? No.

'080 patent, Claim 9? Yes.

Question 5. Do you find that Ferring has proven by clear and convincing evidence that the following claims of the following patents are invalid for lack of written description:

'914 patent, Claim 7? No.

'080 patent, Claim 2? No.

'080 patent, Claim 9? No.

Question 6. What dollar amount do you determine to be a reasonable royalty to compensate UMN and Finch for Ferring's infringement through the date of the trial?

Running royalty, if any: $815,061.

Upfront payment: $25 million.

THE COURT: Do we have any requests to poll the jury?

MR. DE VRIES: No, Your Honor.

MS. DURIE: Can we please poll the jury?

COURT CLERK: Members of the jury, is this the verdict you have agreed upon?

Juror #1, is this the verdict you have agreed upon?

A JUROR: Yes.

COURT CLERK: Juror #2, is the verdict you have

agreed upon?

16:25:34 A JUROR: Yes.

COURT CLERK: Juror #3, is this the verdict you have agreed upon?

16:25:35 A JUROR: Yes.

16:25:36 COURT CLERK: Juror #4, is this the verdict you have agreed upon?

16:25:39 A JUROR: Yes.

16:25:39 COURT CLERK: Juror #5, is the verdict you have agreed upon?

16:25:42 A JUROR: Yes.

16:25:42 COURT CLERK: Juror #6, is this the verdict you have agreed upon?

16:25:46 A JUROR: Yes.

16:25:47 COURT CLERK: Juror #7, is this the verdict you have agreed upon?

16:25:48 A JUROR: Yes.

16:25:48 COURT CLERK: Juror #8, is this the verdict you have agreed upon?

16:25:53 A JUROR: Yes.

16:25:55 THE COURT: All right. Thank you very much, Mr. Kohler.

16:25:58 Ladies and gentlemen, the parties here had a dispute that they needed your help to resolve and I

16:26:05 appreciate your help. And so on behalf of the Court and the

parties, I want to thank you for your service as jurors in this case. I know everybody has busy lives with work and family and that you all took time away from important things to be here, but we can't have our system of justice without people like yourselves willing to serve.

You are now released. If you want to hang out in the jury room for a minute, I just have one brief thing to discuss with the parties, but I'd to thank you personally for your service if you're interesting in hanging out, but you are now free to go.

Mr. Kohler.

(Jury exits.)

THE COURT: All right. Please be seated. Is there anything else we need to address today?

MR. DE VRIES: Not on behalf of our clients, Your Honor.

MS. DURIE: Not today. We'll need to discuss the schedule obviously for post-trial motions.

THE COURT: Absolutely. So why don't you shoot to get me a proposal within two weeks. If you need additional time, that's find. And of course I need you to follow the instructions in the pretrial order for getting any corrections to the transcript to the court reporter.

MS. DURIE: Understood. Thank you.

THE COURT: Thank you very much. It was a

16:27:42 pleasure to preside over this trial.

16:27:45 COURT CLERK: All rise.

16:27:53 (Court adjourned at 4:27 p.m.)

I hereby certify the foregoing is a true and accurate transcript from my stenographic notes in the proceedings.

/s/ Stacy M. Ingram, RPR
Official Court Reporter
U.S. District Court